

Treprostinil Injection (Remodulin®, generic)

When requesting treprostinil injection, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Treprostinil is indicated for:

- Treatment of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group I to diminish symptoms associated with exercise.
- Patients with pulmonary arterial hypertension who require transition from epoprostenol, to reduce the rate of clinical deterioration.

Approved Off-label Compendial Use

- Chronic thromboembolic pulmonary hypertension (CTEPH)

Coverage Guidelines

Pulmonary Arterial Hypertension (PAH)

The individual must meet the following criteria for initial authorization:

- Has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH) confirmed by right heart catheterization;
- Meets one of the following:
 - Individual is in Functional Class III or IV; OR
 - Individual is in Functional Class II AND has tried or is currently receiving one oral agent OR has tried one inhaled/parenteral prostacycline product for PAH;
- Individual with idiopathic PAH must also meet one of the following:
 - Has had an acute response to vasodilator testing during the right heart catheterization and has tried at least one oral calcium channel blocker (CCB) therapy; OR
 - Did not have an acute response to vasodilator testing; OR
 - Cannot undergo a vasodilator test; OR
 - Cannot take CCB therapy (e.g., right heart failure, decreased cardiac output); OR
 - Has tried one CCB
- Treprostinil injection is prescribed by or in consultation with a pulmonologist or a cardiologist.

The individual must meet both of the following criteria for re-authorization:

- Has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization;
- Treprostinil injection is prescribed by or in consultation with a pulmonologist or a cardiologist.

A short-term supply of treprostinil for up to 30 days will be approved if the patient does not meet the criteria above or if there is insufficient information available.

Chronic Thromboembolic Pulmonary Hypertension

The individual must meet the following criterion for authorization:

- Treprostinil injection is prescribed by or in consultation with a pulmonologist or a cardiologist.

Approval duration (initial & renewal): 12 months

Dosing Recommendations

Treprostinil injection is indicated for subcutaneous or intravenous use only as a continuous infusion. Treprostinil injection is preferably infused subcutaneously, but can be administered by a central intravenous line if the subcutaneous route is not tolerated.

Pulmonary Arterial Hypertension (PAH)

The recommended initial dose is 1.25 ng/kg/min. If this initial dose cannot be tolerated because of systemic effects, reduce the infusion rate to 0.625 ng/kg/min.

Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

The recommended dose is up to 50 ng/kg/min.

References

1. Remodulin® subcutaneous or intravenous infusion [prescribing information]. Research Triangle Park, NC: United Therapeutic; October 2023.
2. Treprostinil intravenous infusion [prescribing information]. Princeton, NJ: Sandoz; October 2018.
3. Lang I, Gomez-Sanchez M, Kneussl M, et al. Efficacy of long-term subcutaneous treprostinil sodium therapy in pulmonary hypertension. *CHEST*. 2006;129:1636-1643.
4. Jensen KW, Kerr KM, Fedullo PF, et al. Pulmonary hypertensive medical therapy in chronic thromboembolic pulmonary hypertension before pulmonary thromboendarterectomy. *Circulation*. 2009;120:1248-1254.
5. Skoro-Sajer N, Bonderman D, Wiesbauer F, et al. Treprostinil for severe inoperable chronic thromboembolic pulmonary hypertension. *J Thromb Haemost*. 2006;5:483-489.
6. Sadushi-Kolici R, Jansa P, Kopec G, et al. Subcutaneous treprostinil for the treatment of severe non-operable chronic thromboembolic pulmonary hypertension (CTREPH): a double-blind, phase 3, randomized controlled trial. *Lancet Respir Med*. 2019;7(3):239-248.
7. Sadushi-Kolici R, Lang IM. Treprostinil for the treatment of chronic thromboembolic pulmonary hypertension. *Expert Rev Respir Med*. 2019 Sept 23:1-7.
8. Ruopp NF, Cockrill BA. Diagnosis and treatment of pulmonary arterial hypertension. A review. *JAMA*. 2022;327(14):1379-1391.
9. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults. Update of the CHEST guideline and Expert Panel Report. *CHEST*. 2019;155(3):565-586.

10. Kim NH, Delcroix M, Jais X, et al. Chronic thromboembolic pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801915.
11. Papamtheakis DG, Poch DS, Fernandes TM, et al. Chronic thromboembolic pulmonary hypertension: JACC focus seminar. *J Am Coll Cardiol*. 2020;76(180):2155-2169.
12. Humbert M, Kovacs G, Hoeper MM, et al, for the ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022 Aug 26. [Online ahead of print].
13. Maron B. Revised definition of pulmonary hypertension and approach to management: a clinical primer. *J Am Heart Assoc*. 2023 April 7. [epub ahead of print].
14. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2024 report). © 2024 Global Initiative for Chronic Obstructive Lung Disease. Available at: <https://goldcopd.org/2024-gold-report/>. Accessed on December 2, 2025.