

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

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