

Remodulin® (treprostinil) injection

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

FDA-approved Indications

- 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)

For initial authorization, the individual must meet the following criteria for approval:

- Has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH) confirmed by right heart catheterization; AND
- Has New York Heart Association (NYHA) functional class III or IV; OR
- For functional class II, the individual is currently receiving or has tried one oral agent OR has tried one inhaled/parenteral prostacyclin product for PAH; AND
- Remodulin is prescribed by or in consultation with a pulmonologist or a cardiologist.
- For idiopathic PAH, the individual must also meet **one** of the following:
 - o 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
 - o Did not have an acute response to vasodilator testing; OR
 - o Cannot undergo a vasodilator test; OR
 - o Cannot take CCB therapy (e.g., right heart failure, decreased cardiac output); OR
 - o Has tried one CCB.

For re-authorization, 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; AND
- Remodulin is prescribed by or in consultation with a pulmonologist or a cardiologist.

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

- Is continuing to benefit from Remodulin therapy (e.g., improving in functional class, or quality of life, or in other hemodynamic or clinical parameters).

Chronic Thromboembolic Pulmonary Hypertension

- Remodulin is prescribed by or in consultation with a pulmonologist or a cardiologist; AND
- For re-authorization, the individual continues to benefit from Remodulin therapy (e.g., improving in functional class, or quality of life, or in other hemodynamic or clinical parameters).

Approval duration (initial & renewal): 12 months

Dosing Recommendations

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

Pulmonary Arterial Hypertension (PAH)

Approve up to 100 nanograms per kilogram per minute subcutaneously or intravenously.

Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

Approve up to 50 nanograms per kilogram per minute subcutaneously or intravenously.

References

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