

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

Remodulin is a prostacyclin vasodilator indicated for:

- Treatment of pulmonary arterial hypertension (PAH; World Health Organization [WHO] Group I) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%)
- Patients 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 an initial authorization, the individual must meet following criteria for approval:

- Has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization **AND**
- Has New York Heart Association (NYHA) functional class III or IV **OR**
- For functional class II, an 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, an individual has had acute vasodilator test done during the right heart catheterization unless he/she was unable to undergo a vasodilator test and meet one of the following:
 - o Had an acute response to vasodilator testing and has tried at least one calcium channel blocker (CCB) therapy unless he/she was unable to take CCB therapy **OR**
 - o Did not have an acute response to vasodilator testing

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

Duration of Approval (initial & renewal): 6 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

PAH WHO Group 1 in patients with NYHA Class II-IV symptoms:

The recommended initial dose for patients new to prostacyclin infusion therapy is 1.25 ng/kg/min. The dose should be increased based on clinical response (increments of 1.25 ng/kg/min per week for the first 4 weeks of treatment, later 2.5 ng/kg/min per week)

Transition from Epoprostenol:

The initial dose of Remodulin should be the same as the current dose the patient is receiving using the external infusion pump at the time of transition.

References

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