

## Remodulin® (treprostinil) injection

When requesting 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
- Treprostinil 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
- Trepostinil is prescribed by or in consultation with a pulmonologist or a cardiologist.  
*A short-term supply of trepostinil 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 trepostinil therapy (e.g., improving in functional class, or quality of life, or in other hemodynamic or clinical parameters).

### **Chronic Thromboembolic Pulmonary Hypertension**

- Trepostinil is prescribed by or in consultation with a pulmonologist or a cardiologist; AND
- For re-authorization, the individual continues to benefit from trepostinil 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**

Trepostinil is indicated for subcutaneous or intravenous use only as a continuous infusion. Trepostinil 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 dose is up to 100 nanograms per kilogram per minute administered subcutaneously or intravenously.

#### **Chronic Thromboembolic Pulmonary Hypertension (CTEPH)**

The recommended dose is up to 50 nanograms per kilogram per minute administered subcutaneously or intravenously.

## References

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