MEDICAL MUTUAL®

Drug Policy

Policy:	**201406**	**Initial Effective Date: 04/28/2014**
Code(s):	**HCPCS J3285**	**Annual Review Date: 03/19/2024**
SUBJECT:	**Remodulin® (treprostinil injection)** **Treprostinil (treprostinil injection)**	**Last Revised Date: 03/19/2024**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

POLICY STATEMENT

This policy involves the use of Remodulin. Prior authorization is recommended for pharmacy and medical benefit coverage of Remodulin. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Remodulin as well as the monitoring required for AEs and long-term efficacy, initial approval requires Remodulin be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations under the medical benefit.

Recommended Authorization Criteria

Coverage of Remodulin is recommended in those who meet the following criteria:

FDA-Approved Indications

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1. **Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].**

Criteria. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following criteria (i, ii, iii, iv, v and vi):

- **i.** The patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
- **ii.** The agent is prescribed by, or in consultation with, a cardiologist or a pulmonologist; AND
- **iii.** The patient meets the following criteria (a and b):
  - **a)** The patient has had a right heart catheterization **[documentation required]**; AND
  - **b)** The results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
- **iv.** The patient meets ONE of the following criteria (a or b):
  - **a)** The patient is in Functional Class III or IV; OR
  - **b)** The patient is in Functional Class II and meets ONE of the following criteria [1 or 2]:
    - **(1)** The patient has tried or is currently receiving one oral agent for PAH (e.g., Tracleer® [bosentan tablets], Letairis® [ambrisentan tablets], Opsumit® [macitentan tablets], Adempas® [riociguat tablets], Revatio® [sildenafil tablets {generic} or suspension], Adcirca® [tadalafil tablets {generic}], Orenitram™ [treprostinil extended-release tablets]) or Uptravi® [selexipag tablets]); OR
    - **(2)** The patient has tried one inhaled or parenteral prostacyclin product for PAH (e.g., Ventavis® [iloprost inhalation solution], Tyvaso® [treprostinil inhalation solution], epoprostenol injection); AND
- **v.** Patients with idiopathic PAH must meet the following criteria (a, b, c, d, or e):
  - **a)** The patient had an acute response to vasodilator testing that occurred during the right heart catheterization (defined as a decrease in mPAP of at least 10 mm Hg to an absolute mPAP of less than 40 mm Hg without a decrease in cardiac output) AND has tried one oral calcium channel blocker (CCB) therapy (e.g., amlodipine, nifedipine extended-release tablets); OR
  - **b)** The patient did not have an acute response to vasodilator testing; OR
  - **c)** The patient cannot undergo a vasodilator test; OR
  - **d)** The patient cannot take CCB therapy (e.g., right heart failure, decreased cardiac output); OR
  - **e)** The patient has tried one CCB (e.g., amlodipine, nifedipine extended-release tablets); OR
- **vi.** For approval of brand name Remodulin, the patient must have tried and failed or have a documented intolerance or contraindication to generic treprostinil.

B) Patients Currently Receiving Remodulin. Approve for the duration noted below if the patient meets the following criteria (i, AND ii OR iii):

- **i.** For approval of brand name Remodulin, the patient must have tried and failed or have a documented intolerance or contraindication to generic Treprostinil; AND
- **ii.** Approve if the patient meets ALL of the following conditions (a, b and c):
  - **a)** The patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
  - **b)** The agent is prescribed by, or in consultation with, a cardiologist or a pulmonologist; AND
  - **c)** The patient meets the following criteria (1 and 2):
    - **(1)** The patient has had a right heart catheterization; AND
    - **(2)** The results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; OR

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iii. Approve a short-term supply of Remodulin for up to 14 days if the patient does not meet the criteria in 1Bi above or if there is insufficient information available. Note: a 14-day supply should be sufficient to address coverage issues. However, a maximum of two approvals are allowed if a coverage determination cannot be made. Abrupt discontinuation of Remodulin may have severe adverse consequences.

Dosing in Pulmonary Arterial Hypertension (PAH). *Dosing must meet ONE of the following (A OR B)*:

A) In adults, Remodulin is given subcutaneously (SC) or intravenously (IV) as a continuous infusion. The preferred route is SC but it can be given by a central intravenous line if the SC route is not tolerated. Therapy is initiated at 1.25 ng per kg per min and is adjusted according to response (PAH symptom relief) or adverse effects. Patients are carefully monitored as the dose is adjusted. If this initial dose is not tolerated because of systemic adverse events, reduce the infusion rate to 0.625 ng per kg per min ideal body weight and should be increased cautiously. In a pivotal clinical trial the dose averaged 9.3 ng per kg per min at Week 12. There is little experience with doses > 40 ng per kg per min, but higher doses have been utilized. At the end of a 1-year open-label trial, the average dose was 98 ng per kg per min. An absolute maximum dosage has not been established. With chronic use, it is expected that the dose will be increased if PAH symptoms persist, recur, or worsen; OR

B) In children and adolescents, studies with Remodulin involving children and adolescents used similar dosing to that of adults. In a small (n = 13) analysis involving children and adolescents (mean age 11 years, range 3 to 17 years), the mean Remodulin dose at 12 months was 86 ng per kg per min. An absolute maximum dosage has not been established.

Initial Approval/Extended Approval.

A) *Initial Approval:* Approve for 6 months.

B) *Extended Approval:* Approve at 6-month intervals if the patient is benefiting from the agent as determined by the prescribing physician (e.g., improving in functional class or quality of life, or in other hemodynamic or clinical parameters).

Since PAH is a progressive disease, patients will deteriorate despite therapy.

Duration of Therapy in PAH. Indefinite in patients who are responding or benefiting as defined by the prescribing physician.

Labs/Diagnostics. The patient has had a right heart catheterization (with documentation for initial therapy) to confirm the proper diagnosis of WHO Group 1 PAH.

Other Uses with Supportive Evidence

1. Chronic Thromboembolic Pulmonary Hypertension (CTEPH) [21, 22, 23]

Criteria. *Patient must meet the following criteria (A, B, and C):*

A. The patient has a diagnosis of CTEPH (WHO Group 4); AND

B. The patient has been treated surgically, or CTEPH is inoperable; AND

C. The agent is prescribed by, or in consultation with, a cardiologist or a pulmonologist.

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Dosing in Chronic Thromboembolic Pulmonary Hypertension (CTEPH). [22] *Dosing must meet the following*:

A. Per phase 3 randomized control trial, Remodulin is given subcutaneously (SC) with a target dose of 30 ng per kg per min. An absolute maximum dosage has not been established.

Initial Approval/Extended Approval.

A) *Initial Approval:* Approve for 6 months.

B) *Extended Approval:* Approve at 6-month intervals if the patient is benefiting from the agent as determined by the prescribing physician (e.g., improving in functional class or quality of life, or in other hemodynamic or clinical parameters).

Waste Management for All Indications.

The dose is weight-based and is titrated to efficacy and tolerability. The number of vials should be calculated based on the dose.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3285

Edits and Denials:

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Drug Policy

Prior approval: Prior approval is required for treprostinil injectable **(HCPCS Code J3285)** Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within the Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3285** will edit with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3285	Injection, treprostinil, 1 mg

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