# Clinical Policy: Treprostinil (Remodulin)

Reference Number: LA.PHAR.199
Effective Date: 09.29.23
Last Review Date: 07.18.26
Line of Business: Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

****Please note: This policy is for medical benefit****

**Description**
Treprostinil (Remodulin®) is a prostacyclin analog.

**FDA Approved Indication(s)**
Remodulin is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) to improve exercise ability.

- Remodulin is also indicated to reduce the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol (Flolan®, Veletri®). The risks and benefits of each drug should be carefully considered prior to transition.

For Remodulin, in PAH, studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH, PAH associated with congenital systemic-to-pulmonary shunts, or PAH associated with connective tissue diseases. Nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor) with study duration of 12 weeks.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections® that treprostinil and Remodulin are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Pulmonary Arterial Hypertension** (must meet all)**:**

1. Diagnosis of PAH;
2. Prescribed by or in consultation with a cardiologist or pulmonologist;
3. Failure of a calcium channel blocker (*see Appendix B*), unless member meets one of the following (a or b):
   a. Inadequate response or contraindication to acute vasodilator testing;
   b. Contraindication or clinically significant adverse effects to calcium channel blockers are experienced;

4. If request is for brand Remodulin, member must use generic treprostinil, unless contraindicated or clinically significant adverse effects are experienced;
5. Remodulin: Provider must submit treatment plan detailing pump rate, dose, quantity (in mL), and frequency of cassette change;

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255.
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

**II. Continued Therapy**

**A. Pulmonary Arterial Hypertension** (must meet all)**:**

a. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for brand Remodulin, member must use generic treprostinil, unless contraindicated or clinically significant adverse effects are experienced;
4. Request meets one of the following (a or b):
   a. Remodulin: Provider must submit treatment plan detailing pump rate, dose, quantity (in mL) and frequency of cassette change;
   b. Yutrepia: If request is for a dose increase, new dose does not exceed 848 mcg per day. If member requires titration, provider must submit a titration plan.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255.
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

CTEPH: chronic thromboembolic pulmonary hypertension
FC: functional class
FDA: Food and Drug Administration
FVC: forced vital capacity
mPAP: mean pulmonary arterial pressure
NYHA: New York Heart Association
PA: physical ability
PAH: pulmonary arterial hypertension
PCWP: pulmonary capillary wedge pressure
PH: pulmonary hypertension
PVR: pulmonary vascular resistance
WHO: World Health Organization
WU: Wood Units

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| nifedipine (Procardia XL®)† | 30 mg PO QD; may increase to 60 to 120 mg BID | 240 mg/day |
| diltiazem (Dilt-XR®, Cardizem®, Cardizem® CD, Cartia XT®, Tiazac®, Cardizem® LA, Matzim® LA) † | Immediate release: 40 mg PO TID; may increase to 80 to 240 mg PO TID<br>Extended release: 60 mg PO BID; may increase to 120 to 360 mg BID | 720 mg/day |
| amlodipine (Norvasc®)† | 5 mg PO QD; may increase to 15 to 30 mg/day | 30 mg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*
*†Off-label*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): none reported
- Boxed warnings(s): none reported

*Appendix D: Pulmonary Hypertension: WHO Classification*

- Group 1: PAH
- Group 2: PH due to left heart disease
- Group 3: PH due to lung disease and/or hypoxemia
- Group 4: CTEPH
- Group 5: PH due to unclear multifactorial mechanisms

*Appendix E: Pulmonary Hypertension: WHO/NYHA Functional Classes (FC)*

| Treatment Approach* | FC | Status at Rest | Tolerance of Physical Activity (PA) | PA Limitations | Heart Failure |
|---|---|---|---|---|---|
| Monitoring for progression of PH and treatment of co-existing conditions | I | Comfortable at rest | No limitation | Ordinary PA does not cause undue dyspnea or fatigue, chest pain, or near syncope. | |
| Advanced treatment of PH with PH-targeted therapy – *see Appendix F*** | II | Comfortable at rest | Slight limitation | Ordinary PA causes undue dyspnea or fatigue, chest pain, or near syncope. | |
| | III | Comfortable at rest | Marked limitation | Less than ordinary PA causes undue dyspnea or fatigue, chest pain, or near syncope. | |
| | IV | Dyspnea or fatigue may be present at rest | Inability to carry out any PA without symptoms | Discomfort is increased by any PA. | Signs of right heart failure |

*PH supportive measures may include diuretics, oxygen therapy, anticoagulation, digoxin, exercise, pneumococcal vaccination. **Advanced treatment options also include calcium channel blockers.

*Appendix F: Pulmonary Hypertension: Targeted Therapies*

| Mechanism of Action | Drug Class | Drug Subclass | Drug | Brand/Generic Formulations |
|---|---|---|---|---|
| Reduction of pulmonary arterial pressure through vasodilation | Prostacyclin* pathway agonist<br><br>**Member of the prostanoid class of fatty acid derivatives.* | Prostacyclin | Epoprostenol | Veletri (IV)<br>Flolan (IV)<br>Flolan generic (IV) |
| | | Synthetic prostacyclin analog | Treprostinil | Orenitram (oral tablet)<br>Remodulin (IV)<br>Tyvaso, Tyvaso DPI (inhalation)<br>Yutrepia (inhalation) |
| | | | Iloprost | Ventavis (inhalation) |
| | | Non-prostanoid prostacyclin receptor (IP receptor) agonist | Selexipag | Uptravi (oral tablet) |

| Mechanism of Action | Drug Class | Drug Subclass | Drug | Brand/Generic Formulations |
|---|---|---|---|---|
| | Endothelin receptor antagonist (ETRA) | Selective receptor antagonist | Ambrisentan | Letairis (oral tablet) |
| | | Nonselective dual action receptor antagonist | Bosentan | Tracleer (oral tablet) |
| | | | Macitentan | Opsumit (oral tablet) |
| | Nitric oxide-cyclic guanosine monophosphate enhancer | Phosphodiesterase type 5 (PDE5) inhibitor | Sildenafil | Revatio (IV, oral tablet, oral suspension) |
| | | | Tadalafil | Adcirca (oral tablet) |
| | | Guanylate cyclase stimulant (sGC) | Riociguat | Adempas (oral tablet) |

## V. Dosage and Administration

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Treprostinil (Remodulin) | 1.25 ng/kg/min SC or IV; can be increased weekly based on clinical response | Based on weight and tolerability |

## VI. Product Availability

| Drug | Availability |
|---|---|
| Treprostinil (Remodulin) | 20 mL vials: 2 mg, 4 mg, 8 mg, 20 mg, 50 mg, 100 mg, 200 mg, 400 mg |

## VII. References

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**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J3285 | Injection, treprostinil, 1mg |

| HCPCS Codes | Description |
|---|---|
| J7686 | Treprostinil, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, 1.74 mg |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Policy created | 05.09.23 | 08.28.23 |
| Annual review: no significant changes; clarified wording surrounding the preference for generic Remodulin; references reviewed and updated. | 04.28.24 | 07.10.24 |
| Annual review: no significant changes; in Appendix B per Clinical Pharmacology, removed commercially unavailable branded products, updated dosing regimens; clarified drugs used for off-label indications; references reviewed and updated | 03.06.25 | 05.19.25 |
| Annual review: in Policy/Criteria, clarified criteria also applies to brand Remodulin; added new dosage form, Yutrepia; references reviewed and updated. | 07.10.25 | 09.30.25 |
| Annual review: removed Yutrepia from policy, as this drug has LDH PDL criteria; added new dosage strengths for Remodulin (2 mg, 4 mg, 8 mg, and 400 mg); extended approval duration from 6 months to 12 months; references reviewed and updated. | 07.18.26 | 10.07.26 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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