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| **Department:** | Pharmacy Management | **Original Approval:** | 12/24/2015 |
| **Policy No:** | PM122 | **Last Approval:** | 10/17/2025 |
| **Policy Title:** | Treprostinil (Remodulin®) Clinical Coverage Criteria | | |
| **Approved By:** | UM Criteria Subcommittee | | |
| **Applicable Line(s) of Business:** | ☒ **Washington Apple Health (Medicaid)**<br>☐ **Behavioral Health Services Only**<br>☒ **Apple Health Expansion**<br>☒ **Medicare Advantage/Special Needs Plan**<br>☒ **Medicare Advantage Only**<br>☒ **Cascade Select** | | |

## Required Clinical Documentation for Review

Documentation required to determine medical necessity for Treprostinil (Remodulin): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service -Diagnosis -Labs/Diagnostics -Dosing and duration requested -Initial/Extended approval -Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan -Prescribed by or in consultation with a specialist, when indicated.

## Background

Treprostinil injection, a prostacyclin vasodilator, is indicated for the treatment of pulmonary arterial hypertension (PAH) [World Health Organization {WHO} Group 1] to:[1,2]

1. **Diminish symptoms associated** with exercise.
2. **Reduce the rate of clinical deterioration** for patients who require transition from epoprostenol.

Treprostinil injection has been used with varying results in patients with chronic thromboembolic pulmonary hypertension (CTEPH).[3-7] Benefits noted include improvement in functional class, six-minute walk distance, and in hemodynamic parameters. Treprostinil injection is sometimes used as a bridge prior to surgery. Limited options are available for patients with CTEPH.

**Disease Overview**

PAH is a serious but rare condition impacting fewer than 20,000 patients in the US. It is classified within Group 1 pulmonary hypertension among the five different groups that are recognized. In this progressive disorder the small arteries in the lungs become narrowed, restricted, or blocked causing the heart to work harder to pump blood, leading to activity impairment.[8,9] In time, right-sided heart failure and/or death may occur. Common PAH symptoms include shortness of breath, fatigue, chest pain, dizziness, and fainting, along with impairment in activity tolerance. It is more prevalent in women. Patients of all ages may develop the disease; however, the mean age of diagnosis typically happens between 36 to 50 years. Children may also have PAH. This condition may occur due to various underlying medical conditions or as a disease that uniquely impacts the pulmonary circulation; both genetic and environmental factors may be involved. PAH is defined as a mean pulmonary artery pressure ≥ 25 mmHg with a pulmonary capillary wedge pressure ≤ 15 mmHg measured by cardiac catheterization. The prognosis in PAH has been described as poor, with the median survival being approximately 3 years. However, primarily due to advances in pharmacological therapies, the long-term prognosis has improved. Lung transplantation may be recommended if pharmacological or medical therapies fail, based upon patient status. The WHO categorizes PAH into stages, which is also referred to as the functional class (Class I to IV) and is an adaptation of the New York Heart Association system to evaluate activity tolerance.
CTEPH is a persistent obstruction of pulmonary arteries and is often a complication of pulmonary embolism.[10,11] It is classified within Group 4 pulmonary hypertension. Symptoms include progressive dyspnea on exertion, as well as fatigue, syncope, hemoptysis, and signs of right heart failure. Pulmonary endarterectomy is the treatment of choice for most patients with CTEPH. However, around 40% of patients are deemed inoperable for various reasons. Medication therapy may also be recommended. Anticoagulant therapy is also given.

**Guidelines**

Several guidelines address treprostinil injection in the management of pulmonary hypertension.[9,12]

- **Pulmonary Arterial Hypertension:** An updated CHEST guideline and Expert Panel Report regarding therapy for PAH in adults (2019) provides the evidence for use of the many medications for this condition.[9] In the absence of contraindications, patients with PAH should undergo acute vasoreactivity testing utilizing a short-acting agent (e.g., calcium channel blockers). For patients in Functional Class II, oral therapies are recommended such as endothelin receptor antagonists (Letairis® [ambrisentan tablets], Tracleer® [bosentan tablets], Opsumit® [macitentan tablets]), phosphodiesterase type 5 inhibitors (tadalafil, sildenafil), and Adempas® (riociguat tablets). It is suggested that parenteral or inhaled prostanoids not be chosen as initial therapy for treatment naïve patients with PAH with WHO Functional Class II symptoms or as second-line agents for patients with

PAH with WHO Functional Class II who have not met their treatment goals. Parenteral prostanoids are recommended for patients with PAH in Functional Class III and IV.[9] The European Society of Cardiology (ESC) and the European Respiratory Society (ERS) guidelines regarding the treatment of pulmonary hypertension (2022) also recognize parenteral treprostinil as having a prominent role in the management of this condition, usually in later therapy stages and after other therapies.[12]

- **Chronic Thromboembolic Pulmonary Hypertension:** Guidelines from the ESC/ERS regarding the treatment of pulmonary hypertension (2022) recommended to consider parenteral prostacyclin analogs for patients with inoperable CTEPH.[12]

**Safety**

Treprostinil injection should not be abruptly discontinued or have the dose rapidly decreased as rebound pulmonary hypertension may occur.[1,2]

**Policy Statement**

This policy involves the use of Remodulin. Prior authorization is recommended for medical benefit coverage of Remodulin. Coverage is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial or Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Remodulin as well as the monitoring required for adverse events and long-term efficacy, approval requires Remodulin to 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 required, a response to therapy is required for continuation of therapy.

**Documentation:** Documentation is required for initiation of therapy where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes and catheterization laboratory results. For a patient case in which the documentation requirement of the right heart catheterization upon Prior Authorization coverage review for a different medication indicated for WHO Group 1 PAH has been previously provided, the documentation requirement is considered to be met.

## Definitions

None.

## Indications/Criteria

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| **Medicaid Members** | ***Continue to criteria for approval below.***<br>***Preferred Product: generic treprostinil***<br>***Non-Preferred Procut: brand Remodulin*** |
| **Individual & Family (Cascade Select) Members** | ***Continue to criteria for approval below.***<br>***Preferred Product: generic treprostinil***<br>***Non-Preferred Procut: brand Remodulin*** |
| **Medicare Members** | ***Continue to criteria for approval below.***<br>***Preferred Product: generic treprostinil***<br>***Non-Preferred Procut: brand Remodulin*** |

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

**FDA-Approved Indications**

1. **Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has had a right heart catheterization **[documentation required]** (see documentation section above); AND
       - **b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient is in Functional Class III or IV; OR
       - **b)** Patient is in Functional Class II and meets ONE of the following [(1) or (2)]:
         - **(1)** Patient has tried or is currently receiving one oral agent for PAH; OR
           Note: Examples of oral agents for PAH include bosentan, ambrisentan, Opsumit (macitentan tablets), Opsynvi (macitentan/tadalafil tablets), Adempas (riociguat tablets), sildenafil, tadalafil, Alyq (tadalafil tablets), Tadliq

(tadalafil oral suspension), Orenitram (treprostinil extended-release tablets), and Uptravi (selexipag tablets).

**(2)** Patient has tried one inhaled or parenteral prostacyclin product for PAH; AND
Note: Examples of inhaled and parenteral prostacyclin products for PAH include Ventavis (iloprost inhalation solution), Tyvaso (treprostinil inhalation solution), Tyvaso DPI (treprostinil oral inhalation powder), and epoprostenol intravenous infusion (Flolan, Veletri, generics).

**iv.** Patient with idiopathic PAH must meet ONE of the following (a, b, c, d, or e):

**a)** Patient meets BOTH of the following [(1) and (2)]:

**(1)** According to the prescriber, the patient has had an acute response to vasodilator testing that occurred during the right heart catheterization; AND
Note: An example of a response can be defined as a decrease in mean pulmonary artery pressure of at least 10 mm Hg to an absolute mean pulmonary artery pressure of less than 40 mm Hg without a decrease in cardiac output.

**(2)** Patient has tried one calcium channel blocker (CCB) therapy; OR
Note: Examples of CCBs include amlodipine and nifedipine extended-release tablets.

**b)** According to the prescriber, the patient did not have an acute response to vasodilator testing; OR

**c)** According to the prescriber, the patient cannot undergo a vasodilator test; OR

**d)** Patient cannot take CCB therapy; OR
Note: Examples of reasons patients cannot take CCB therapy include right heart failure or decreased cardiac output.

**e)** Patient has tried one CCB; AND
Note: Examples of CCBs include amlodipine and nifedipine extended-release tablets.

**v.** Medication is prescribed by or in consultation with a cardiologist or a pulmonologist; OR

**B)** Patient Currently Receiving Treprostinil Injection. Approve for the duration noted below if the patient meets ONE of the following (i or ii):

**i.** Approve for 1 year if the patient meets ALL of the following (a, b, and c):

**a)** Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND

**b)** Patient meets BOTH of the following [(1) and (2)]:

**(1)** Patient has had a right heart catheterization; AND
Note: This refers to prior to starting therapy with a medication for WHO Group 1 PAH.

**(2)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND

**c)** Medication is prescribed by or in consultation with a cardiologist or a pulmonologist; OR

**ii.** Approve a short-term supply of treprostinil injection for up to 14 days if the patient does not meet the criteria in 1Bi above or if there is insufficient information available. All approvals are reviewed by a nurse or pharmacist.
Note: A 14-day supply should be sufficient to address coverage issues. However, multiple short-term approvals are allowed if a coverage determination cannot be made. Abrupt discontinuation of treprostinil injection therapy may have severe adverse consequences.

**Dosing.** Approve up to 100 ng/kg/minute given subcutaneously or intravenously.

**Other Uses with Supportive Evidence**

**2. Chronic Thromboembolic Pulmonary Hypertension (CTEPH).** Approve for 1 year if the agent is prescribed by or in consultation with a pulmonologist or a cardiologist.

**Dosing.** Approve up to 50 ng/kg/minute subcutaneously or intravenously.

**Recommended Exception Criteria**

| Non-Preferred Product | Exception Criteria |
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| **Medicaid/ Individual & Family (Cascade Select)** Remodulin | **1.** Approve for 1 year if the patient meets BOTH of the following (A and B):<br>**A)** Patient meets the treprostinil criteria; AND<br>**B)** Patient meets ONE of the following (i or ii):<br>**i.** If the request is for Remodulin for subcutaneous continuous infusion, the patient meets ONE of the following (a or b):<br>**a)** For Initial Therapy or Patient is Currently Receiving Remodulin for < 90 days, patient meets ONE of the following [(1) or (2)]:<br>**(1)** Patient meets BOTH of the following [(a) and (b)]:<br>**(a)** Patient has tried generic treprostinil for subcutaneous continuous infusion **[documentation required]**; AND<br>**(b)** Patient cannot take generic treprostinil for subcutaneous continuous infusion due to a formulation difference in the inactive ingredients(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant |

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| | allergy or serious adverse reaction **[documentation required]**; OR<br>**(2)** Patient cannot take generic treprostinil because appropriate durable medical equipment is not available such as the patient does not have or cannot obtain a compatible pump that allows generic treprostinil to be administered; OR<br>**b)** For a Patient Currently Receiving Remodulin for ≥ 90 days, patient meets ONE of the following [(1) or (2)]:<br>**(1)** Patient meets BOTH of the following [(a) and (b)]:<br>**(a)** Patient has been started on therapy for ≥ 90 days **[documentation required]**; AND<br>**(b)** Patient has a history of medical or prescription pharmacy paid claims **[documentation or verification required]**; OR<br>**(2)** Patient cannot take generic treprostinil because appropriate durable medical equipment is not available such as the patient does not have or cannot obtain a compatible pump that allows generic treprostinil to be administered; OR<br>**ii.** If the request is for Remodulin for intravenous continuous infusion, patient meets BOTH of the following (a and b):<br>**a)** Patient has tried generic treprostinil for intravenous continuous infusion **[documentation required]**; AND<br>**b)** Patient cannot take generic treprostinil for intravenous continuous infusion due to a formulation difference in the inactive ingredients(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. |
| **Medicare**<br>Remodulin | **1.** Approve for 1 year if the patient meets BOTH of the following (A and B):<br>**A)** Patient meets the treprostinil criteria; AND<br>**B)** Patient meets ONE of the following (i or ii):<br>**i.** If the request is for Remodulin for subcutaneous continuous infusion, the patient meets ONE of the following (a, b or c):<br>**a)** Patient meets BOTH of the following [(1) and (2)]:<br>**(1)** Patient has tried generic treprostinil for subcutaneous continuous infusion **[documentation required]**; AND<br>**(2)** Patient cannot take generic treprostinil for subcutaneous continuous infusion due to a formulation difference in the inactive ingredients(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the |

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| | prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**; OR<br>**b)** Patient cannot take generic treprostinil because appropriate durable medical equipment is not available such as the patient does not have or cannot obtain a compatible pump that allows generic treprostinil to be administered; OR<br>**c)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.<br>**ii.** If the request is for Remodulin for intravenous continuous infusion, patient meets ONE of the following (a or b):<br>**a)** Patient meets BOTH of the following [(1) and (2)]:<br>**(1)** Patient has tried generic treprostinil for intravenous continuous infusion **[documentation required]**; AND<br>**(2)** Patient cannot take generic treprostinil for intravenous continuous infusion due to a formulation difference in the inactive ingredients(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**; OR<br>**b)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days. |

**Conditions Not Recommended for Approval**

Coverage of treprostinil injection is not recommended in the following situations:

1. **Chronic Obstructive Pulmonary Disease (COPD) in a Patient Without PAH (WHO Group 1).** COPD is classified as Group 3 Pulmonary Hypertension (pulmonary hypertension associated with lung diseases and/or hypoxia). Pulmonary hypertension may develop late in the course of COPD, but medications used for the treatment of PAH (WHO Group 1) are not recommended therapies.[12]
2. **Concurrent Use with Parenteral Epoprostenol Products, Oral Prostacyclin Products, or Inhaled Prostacyclin Agents Used for Pulmonary Hypertension**.
   Note: Examples of medications include Orenitram (treprostinil extended-release tablets), Uptravi (selexipag tablets and intravenous infusion), Tyvaso (treprostinil inhalation solution), Tyvaso DPI (treprostinil oral inhalation powder), Ventavis (iloprost inhalation solution), and epoprostenol injection (Flolan, Veletri, generic).

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Special Considerations

None.

## Limitations/Exclusions

Please see link to member coverage documents below:

| Line of Business | Link to Member Coverage Documents |
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| Medicare Advantage Plans (Including D-SNP) | https://medicare.chpw.org/<br>Select the appropriate plan from the "Plans" drop down on the top navigation bar. |
| Apple Health | https://www.chpw.org/for-members/benefits-and-coverage-imc/ |
| Individual & Family (Cascade Select) | https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/ |

## Citations & References

| | | |
|---|---|---|
| **CFR** | 42 CFR § 438.210 | |
| **WAC** | 284-43-2050 | |
| **RCW** | | |
| **LOB & Contract Citation** | ☒ **WAHIMC**<br>☐ **BHSO**<br>☐ **Wraparound**<br>☐ **SMAC**<br>☐ **HH** | IMC Section 11.3: Medical Necessity Determination |
| | ☐ **AHE** | |
| | ☒ **MA/DSNP** | P&P supports all LOB requirements |
| | ☒ **CS** | P&P supports all LOB requirements |
| **Other Requirements** | | |
| **NCQA Elements** | | |

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| **References** | 1. Remodulin® subcutaneous or intravenous infusion [prescribing information]. Research Triangle Park, NC: United Therapeutic; July 2021.<br>2. Treprostinil intravenous infusion [prescribing information]. Princeton, NJ: Sandoz; October 2018.<br>3. Lang I, Gomez-Sanchez M, Kneussl M, et al. Efficacy of long-term subcutaneous treprostinil sodium therapy in pulmonary hypertension. *CHEST*. 2006;129:1636-1643.<br>4. Jensen KW, Kerr KM, Fedullo PF, et al. Pulmonary hypertensive medical therapy in chronic thromboembolic pulmonary hypertension before pulmonary thromboendarterectomy. *Circulation*. 2009;120:1248-1254.<br>5. Skoro-Sajer N, Bonderman D, Wiesbauer F, et al. Treprostinil for severe inoperable chronic thromboembolic pulmonary hypertension. *J Thromb Haemost.* 2006;5:483-489.<br>6. Sadushi-Kolici R, Jansa P, Kopec G, et al. Subcutaneous treprostinil for the treatment of severe non-operable chronic thromboembolic pulmonary hypertension (CTREPH): a double-blind, phase 3, randomized controlled trial. *Lancet Respir Med*. 2019;7(3):239-248.<br>7. Sadushi-Kolici R, Lang IM. Treprostinil for the treatment of chronic thromboembolic pulmonary hypertension. *Expert Rev Respir Med*. 2019 Sept 23:1-7.<br>8. Ruopp NF, Cockrill BA. Diagnosis and treatment of pulmonary arterial hypertension. A review. *JAMA*. 2022;327(14):1379-1391.<br>9. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults. Update of the CHEST guideline and Expert Panel Report. *CHEST*. 2019;155(3):565-586.<br>10. Kim NH, Delcroix M, Jais X, et al. Chronic thromboembolic pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801915.<br>11. Papamatheakis DG, Poch DS, Fernandes TM, et al. Chronic thromboembolic pulmonary hypertension: JACC focus seminar. *J Am Coll Cardiol*. 2020;76(180):2155-2169.<br>12. Humbert M, Kovacs G, Hoeper MM, et al, for the ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022 Aug 26. [Online ahead of print].<br>13. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2021 report). © 2020 Global Initiative for Chronic |

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| | Obstructive Lung Disease. Available at: https://goldcopd.org/wp-content/uploads/2020/11/GOLD-REPORT-2021-v1.1-25Nov20_WMV.pdf. Accessed on September 5, 2023. |

## Revision History

| Revision Date | Revision Description | Revision Made By |
|---|---|---|
| 12/23/2015 | New | Kelly Force; Yusuf Rashid, RPh |
| 12/24/2015 | Approval | MMLT |
| 01/11/2017 | No revisions | Fran McGaugh |
| 01/12/2017 | Approval | MMLT |
| 07/24/2017 | Criteria completely updated and revised | Michael Sporck, Pharmacy Intern Sophia Yun, PharmD |
| 07/25/2017 | Approved | MMLT |
| 03/09/2018 | Reassigned from UM to PM | Cindy Bush |
| 04/25/2018 | Transferred to new template | Cindy Bush |
| 06/08/2018 | No revisions | Jennifer Farley, PharmD |
| 06/14/2018 | Approval | UM Committee |
| 04/03/2019 | Annual review. No changes | Ivan Figueira, PharmD |
| 05/09/2019 | Approval | UM Pharmacy Subcommittee |
| 02/24/2020 | Annual review- The approval durations were changed from 6 months to 1 year. | Jennifer Farley, PharmD |
| 02/27/2020 | Approval | UM Pharmacy Subcommittee |
| 12/31/2020 | Annual review. No changes | Jennifer Farley, PharmD |
| 01/07/2021 | Approval | UM Pharmacy Subcommittee |

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| 01/03/2022 | Annual review. No changes | Roxy Duan, PharmD Candidate<br>Alan Gabot, PharmD |
| 01/06/2022 | Approval | UM Pharmacy Subcommittee |
| 11/03/2022 | Annual review. No changes | Alan Gabot, PharmD |
| 11/14/2022 | Approval | UM Pharmacy Subcommittee |
| 09/06/2023 | Annual review. Added Tadliq (tadalafil oral suspension) as an example of an oral agent for pulmonary arterial hypertension (PAH). Added Tyvaso DPI (treprostinil oral inhalation powder) as an example of an inhaled prostacyclin product for PAH Removed requirement to send cases to the medical director in cases where the patient is currently receiving Remodulin and does not meet criteria 1Bi or if there is insufficient information available. Updated background information. Added the following condition not recommended for approval: concurrent use with parenteral epoprostenol products, oral prostacyclin products, or inhaled prostacyclin agents used for pulmonary hypertension. Removed appendix A regarding classification of pulmonary arterial hypertension. Created criteria to require patients try generic treprostinil prior to using brand Remodulin. | Alan Gabot, PharmD |
| 09/07/2022 | Approval | UM Pharmacy Subcommittee |
| 06/11/2024 | Annual review. No changes. | Alan Gabot, PharmD |
| 06/12/2024 | Approval | UM Criteria Subcommittee |
| 12/10/2024 | Early update. Updated step therapy criteria for brand Remodulin | Alan Gabot, PharmD |

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| 12/11/2024 | Approval | UM Criteria Subcommittee |
| 10/08/2025 | Early update. Separated non-preferred criteria from the clinical criteria and placed it in the Recommended Exception Criteria | Alan Gabot, PharmD |
| 10/17/2025 | Approval | UM Criteria Subcommittee |