PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Pulmonary Arterial Hypertension – Treprostinil Injection Preferred Specialty Management Policy

- Remodulin® (treprostinil subcutaneous or intravenous infusion – United Therapeutics, generic)

REVIEW DATE: 06/01/2022; selected revision 08/31/2022

OVERVIEW

Treprostinil injection, a prostacyclin vasodilator, is indicated for the treatment of **pulmonary arterial hypertension** (World Health Organization Group 1) to diminish symptoms associated with exercise and reduce the rate of clinical deterioration for patients who require transition from epoprostenol.[1,2]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Pulmonary Arterial Hypertension – Treprostinil Injection Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Pulmonary Arterial Hypertension – Treprostinil Injection Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. All approvals are provided for 1 year in duration.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, claims records, and/or other information. For certain criteria, verification is an option as noted by **[verification required]**.

Automation: None.

Preferred Product: generic treprostinil injection
Non-Preferred Product: Remodulin

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Remodulin	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Treprostinil Injection Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** If the request is for Remodulin for subcutaneous continuous infusion, the patient meets one of the following (a or b): **a)** For Initial Therapy or Patient is Currently Receiving Remodulin for < 90 Days, patient meets one of the following [(1) or (2)]: **(1)** Patient meets both of the following [(a) and (b)]: **(a)** Patient has tried generic treprostinil for subcutaneous continuous infusion **[documentation required]**; AND **(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 allergy or serious adverse reaction **[documentation required]**; OR **(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 **b)** For a Patient Currently Receiving Remodulin for ≥ 90 days, patient meets one of the following [(1) or (2)]: **(1)** Patient meets both of the following [(a) or (b)]: **(a)** Patient has been started on therapy for ≥ 90 days **[documentation required]**; AND **(b)** Patient has a history of medical or prescription pharmacy paid claims **[documentation or verification required]**. **(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 **ii.** If the request is for Remodulin for intravenous continuous infusion, patient meets one of the following (a or b): **a)** For Initial Therapy or Patient is Currently Receiving Remodulin for < 90 Days, patient meets both of the following [(1) and (2)]: **(1)** Patient has tried generic treprostinil for intravenous continuous infusion **[documentation required]**; AND **(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 **b)** For a Patient Currently Receiving Remodulin for ≥ 90 days patient meets both of the following [(1) and (2)]:

	(1) Patient has been started on therapy for ≥ 90 days **[documentation required]**; AND **(2)** Patient has a of medical or prescription pharmacy paid claims **[documentation or verification required]**. **2.** If the patient has met the standard *Pulmonary Arterial Hypertension – Treprostinil Injection Prior Authorization Policy* criteria (1A), but has not met exception criteria Bi or Bii above for brand Remodulin, approve generic treprostinil injection.

REFERENCES

1. Remodulin® subcutaneous or intravenous infusion [prescribing information]: Research Triangle Park, NC: United Therapeutics; July 2021.
2. Treprostinil subcutaneous or intravenous infusion [prescribing information]. Princeton, NJ: Sandoz; April 2019.