**This policy applies to the following:**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| ✓ | Standard Control (SF) | | Managed Medicaid Template (MMT) | ✓ | ACSF Chart (ACSFC) | | Medical Benefit | | Medicare Part B |
| | Preferred Drug Plan Design (PDPD) | | Marketplace (MF) | ✓ | SF Chart (SFC) | | Medical Benefit: Biosimilars First | | Medicare Part B: Biosimilars First |
| ✓ | Advanced Control Specialty (ACSF) | | New to Market (NTM) | ✓ | VF Chart (VFC) | | Medical Benefit: Add-on | | Medicare Part B: Advanced Biosimilars First |
| ✓ | Value (VF) | | Aetna Health Exchange (AHE) | | | | Medical Benefit: Managed Medicaid | | |
| | | | IVL | | | | | | |

| Reference # |
|---|
| 4527-D |

# EXCEPTIONS CRITERIA

## PULMONARY ARTERIAL HYPERTENSION (PAH) INTRAVENOUS

## PREFERRED PRODUCT: TREPROSTINIL INTRAVENOUS INJECTION

### POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

### I. PLAN DESIGN SUMMARY

This program applies to the intravenous Pulmonary Arterial Hypertension (PAH) products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

**Table. Intravenous PAH Products**

| | Product(s) |
|---|---|
| **Preferred*** | • **treprostinil** intravenous injection (generic) |
| **Targeted** | • **Remodulin** (treprostinil) intravenous injection |

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

### II. EXCEPTION CRITERIA

Coverage for Remodulin intravenous injection is provided when any of the following criteria is met:

A. Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
B. Member is currently receiving treatment with the targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
C. Member is physically or otherwise unable to mix their medication and is enrolled in a Remodulin SPmix Program.

### REFERENCES


1. Remodulin [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; July 2021.
2. Treprostinil [package insert]. Princeton, NJ: Sandoz Inc.; April 2019.







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