Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 62.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Remodulin IV (treprostinil sodium)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Remodulin IV (treprostinil sodium)

II. Purpose/Objective:
To provide a policy of coverage regarding Remodulin IV (treprostinil sodium)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Remodulin IV (treprostinil sodium) is a type of medication called a prostaglandin analog which helps the body open blood vessels located within pulmonary and systemic vascular beds.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Remodulin IV (treprostinil sodium) will be considered medically necessary for the Commercial, Exchange, CHIP, and Medicaid lines of business when all of the following criteria are met:

- Must be prescribed by a pulmonologist or cardiologist **AND**
    - Physician provided documentation of a diagnosis of class 4 pulmonary arterial hypertension **OR**
    - Physician provided documentation of a diagnosis of class 2 or 3 pulmonary arterial hypertension with therapeutic failure on, intolerance to or contraindication to; one (1) formulary preferred agent which is approved or medically accepted for the beneficiary's diagnosis or indication, from any of the following classes of medications
        - Endothelin Receptor Antagonist
        - Phosphodiesterase-5 Enzyme Inhibitor
        - Prostacyclin

    OR
    - Individuals who require transition from Flolan, to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition

AND

- If a brand drug is being requested when a therapeutically equivalent generic drug exists:
    - Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
    - Medical record documentation of an intolerance to or contraindication to the inactive ingredients of the generic formulary agent(s)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

Remodulin IV (treprostinil sodium) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Must be prescribed by a pulmonologist or cardiologist **AND**
    - Physician provided documentation of a diagnosis of class 4 pulmonary arterial hypertension **OR**
    - Physician provided documentation of a diagnosis of class 2 or 3 pulmonary arterial hypertension with therapeutic failure on, intolerance to or contraindication to; one (1) formulary preferred agent which is approved or medically accepted for the beneficiary's diagnosis or indication, from any of the following classes of medications
        - Endothelin Receptor Antagonist
        - Phosphodiesterase-5 Enzyme Inhibitor
        - Prostacyclin

    OR
    - Individuals who require transition from Flolan, to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Remodulin [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp; July 2021.
2. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults. American College of Chest Physicians (CHEST). CHEST Journal; 2019 March; 155(3):565-586 [cited 2023 Dec 27]. Available from: https://journal.chestnet.org/article/S0012-3692(19)30002-9/fulltext

This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/9/08

Revised: 6/10; 2/12 (criteria), 09/16/14 (removed Tracleer as formulary alternative) 3/18/15 (formatting), 9/5/17 (Ventavis removed), 5/31/19 (auth duration), 7/9/19 (grandfather), 3/12/21 (per DHS, form alt), 1/19/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment), 12/31/23 (references added), 1/18/23 (added generic drug language), 1/16/25 (LOB table, taglines)

Reviewed: 11/09; 10/11; 4/14, 11/2/2015, 9/28/16, 7/31/17, 7/10/18, 2/1/20, 1/28/21, 1/21/22

MA UM Committee approval: 12/31/23, 12/31/24, 4/29/25

DHS PARP approval: 6/5/25