Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 61.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Flolan or Veletri (epoprostenol)

I. Policy:
Flolan or Veletri (epoprostenol)

II. Purpose/Objective:
To provide a policy of coverage regarding Flolan or Veletri (epoprostenol)

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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:
Flolan or Veletri (epoprostenol) is a man-made form of a naturally occurring molecule in the human body called prostaglandin which helps the body open blood vessels.

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

Flolan or Veletri (epoprostenol) will be considered medically necessary for Commercial, Exchange, and CHIP 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
- In patient without cardiopulmonary comorbidities who have a vasoreactivity test of negative and high risk or increase risk of mortality allow, documentation of use in combination with sildenafil AND bosentan

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 a therapeutic failure on, 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.

Flolan or Veletri (epoprostenol) will be considered medically necessary for the Medicaid 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

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 a therapeutic failure on, 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.

Flolan or Veletri (epoprostenol) will be considered medically necessary for 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 2, 3 or 4 pulmonary arterial hypertension

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.

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. Flolan [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2023.
2. Veletri [prescribing information]. Titusville, NJ: Actelion Pharmaceuticals US Inc; July 2022.

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

Devised: 06/23/08

Revised: 6/10, 09/16/14 (removed Tracleer as formulary alternative), 03/24/15, 5/19/17 (removed Ventavis as alternative), 4/19/19 (grandfather language), 2/10/21 (per DHS, form alt), 12/19/22 (LOB carve out, Medicaid PARP statement), 12/6/23 (Medicaid business segment, added generic drug language, references), 5/21/24 (added cardiopulmonary)

Reviewed: 11/09; 10/11; 1/14, 3/16, 3/30/17, 3/29/18, 3/28/19, 1/1/20, 1/1/21, 12/21/21

MA UM Committee approval: 12/31/23, 12/31/24