MEDICAL MUTUAL®

Drug Policy

Policy: CC	Orenitram (treprostinil)	Annual Review Date: 02/20/2025 Last Revised Date: 02/20/2025

OVERVIEW

Orenitram, a prostacyclin mimetic, is indicated for the treatment of **pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1** to delay disease progression and to improve exercise capacity.

POLICY STATEMENT

This policy involves the use of Orenitram. Prior authorization is recommended for pharmacy benefit coverage of Orenitram. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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

RECOMMENDED AUTHORIZATION CRITERIA

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

1. Pulmonary Arterial Hypertension (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 criteria (i, ii, iii, and iv):

- **i.** Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
- **ii.** Patient meets the following criteria (a and b):
  - **a)** Patient has had a right heart catheterization*; AND
  - **b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
- **iii.** Patient meets one of the following conditions (a or b):
  - **a)** Patient has tried or is currently receiving at least one oral medical for PAH from the following different categories (either alone or in combination) each for ≥ 60 days: one phosphodiesterase type 5 (PDE5) inhibitor, one endothelin receptor antagonist (ERA), or Adempas (riociguat tablets); OR

Note: Examples of phosphodiesterase type 5 inhibitors include sildenafil and tadalafil . Examples of endothelin receptor antagonists include bosentan, ambrisentan, and Opsumit (macitentan tablets). Opsynvi (macitentan/tadalafil tablets) is a combination product containing a phosphodiesterase type 5 inhibitor and endothelin receptor antagonist.

b) Patient is receiving or has received in the past one PAH prostacyclin therapy or a prostacyclin receptor agonist (i.e., Uptravi [selexipag tablets]) for PAH; AND
Note: Examples of prostacyclin therapies for PAH include Tyvaso (treprostinil inhalation solution), Tyvaso DPI (treprostinil oral inhalation), Ventavis (iloprost inhalation solution), treprostinil injection, and epoprostenol injection; AND

iv. Medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

B) Patient is Currently Receiving Orenitram. Approve for 1 year if the patient meets all of the following criteria (i, ii, iii, and iv):

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

ii. Patient meets the following (a and b):
   i. Patient has had a right heart catheterization; AND
   Note: This refers to prior to starting therapy with a medication for WHO Group 1 PAH.
   ii. Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH); AND

iii. The medication is prescribed by, or in consultation with, a cardiologist or a pulmonologist; AND

iv. The patient is experiencing a beneficial response to treatment with Orenitram, including any of the following: reduced pulmonary vascular resistance and/or pressure, improved symptoms, and/or improved patient activity.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Orenitram has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent Use with Uptravi (selexipag tablets and intravenous infusion), Inhaled Prostacyclin Products, or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.**
   Note: Examples of medications include Tyvaso (treprostinil inhalation solution), Tyvaso DPI (treprostinil oral inhalation powder), Ventavis (iloprost inhalation solution), epoprostenol intravenous infusion, and treprostinil subcutaneous or intravenous infusion.

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

***Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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