

Commercial/Healthcare Exchange PA Criteria
Effective: 5/11/2018

Prior Authorization: Orenitram (treprostinil)

Products Affected: Orenitram (treprostinil) oral extended release tablets

Medication Description:

Treprostinil diethanolamine is a prostacyclin vasodilator. It directly vasodilates pulmonary and systemic arterial vascular beds, inhibits platelet aggregation, and inhibits smooth muscle cell proliferation. The extended-release formulation uses a semipermeable membrane to create hydrostatic pressure and release the drug at a controlled rate.

Covered Uses: Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity.

Exclusion Criteria:

1. Severe hepatic impairment (Child Pugh Class C)

Required Medical Information:

1. Diagnosis
2. World Health Organization (WHO) functional class
3. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a pulmonologist or a cardiologist

Coverage Duration: 12 months

Other Criteria:

Pulmonary Arterial Hypertension

- A. Patient has clinically documented PAH (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure).

References:

1. Product Information: ORENITRAM(R) oral extended release tablets, treprostinil oral extended release tablets. United Therapeutics Corp (per FDA), Research Triangle Park, NC, 2019.
2. Treprostinil Diolamine. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated April 13, 2020. Accessed June 18, 2020.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/11/2018
2	Annual Review	No Changes; CCI adopted EH policy and template	All	01/14/2020
3	Revision	Coverage duration updated to 12 months Removal of other criteria: Patient must not be using tobacco products Removal of other criteria: NYHA functional class	All	7/1/2020