

**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:**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
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