ConnectiCare

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

Prior Authorization: Tyvaso (treprostinil)

Products Affected: Tyvaso (treprostinil) oral inhalation solution

Medication Description:

The major pharmacological actions of treprostinil are direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation. Studies in animals have demonstrated vasodilatory effects such as, reduction in right and left ventricular afterload and increased cardiac output and stroke volume. Other studies have shown that treprostinil causes a dose-related negative inotropic and lusitropic effect. There were no major effects on cardiac conduction.

Covered Uses: Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability.

Exclusion Criteria: N/A

Required Medical Information:

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

New York Heart Association functional classification:
Class 1: No symptoms with ordinary physical activity.
Class 2: Symptoms with ordinary activity. Slight limitation of activity.
Class 3: Symptoms with less than ordinary activity. Marked limitation activity.
Class 4: Symptoms with any activity or event at rest

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:

Dosing Limitations: Tyvaso has a limitation of one starter kit per year.

Pulmonary Arterial Hypertension

A. Patient has clinically diagnosed primary or secondary PAH (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure); **AND**
B. Patient exhibits Class III or IV symptoms; **AND**
C. Patient has tried and failed, or has a contraindication or intolerance to a calcium channel blocker after favorable response to acute vasoreactivity testing; **OR**

D. Patient has failed to have a pulmonary vasodilator response to an acute challenge of a short acting vasodilator; **AND**

E. Patient has tried and failed or has a contraindication or intolerance to Tracleer (bosentan).

References:

1. Product Information: Tyvaso(R) oral inhalation solution, treprostinil oral inhalation solution. United Therapeutics Corp. (per FDA), Research Triangle Park, NC, 2017.
2. Treprostinil. 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	Changed coverage duration to 12 months Removal under other criteria: Patient must not be using tobacco products.	All	7/1/2020