ConnectiCare

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

Prior Authorization: Tracleer (bosentan)

Products Affected: Tracleer (bosentan) oral tablets, bosentan oral tablets, Tracleer (bosentan) oral tablets for suspension

Medication Description:

Bosentan is a dual endothelin receptor antagonist. Endothelin-1 (ET-1) is a neurohormone, and a potent vasoconstrictor with the ability to promote fibrosis, cell proliferation and tissue remodeling. The effects of which are mediated by binding to ETA and ETB receptors in the endothelium and vascular smooth muscle. ET-1 concentrations are elevated in plasma and lung tissue of patients with pulmonary arterial hypertension, suggesting a pathogenic role for ET-1 in this disease. Bosentan exerts a specific and competitive antagonist at endothelin receptor types ETA and ETB, with a slightly higher affinity for ETA than ETB receptors. Bosentan decreases both pulmonary and systemic vascular resistance resulting in increased cardiac output without increasing heart rate.

Covered Uses:

1. Pulmonary arterial hypertension (PAH) (WHO Group 1) in adults to improve exercise ability and to decrease clinical worsening.
2. Pulmonary arterial hypertension (PAH) (WHO Group 1) in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR).

Exclusion Criteria:

1. Pregnancy
2. Concomitant use with cyclosporine A
3. Concomitant use with glyburide

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: 3 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 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.

References:

1. Product Information: TRACLEER(R) oral tablets, tablets for oral suspension, bosentan oral tablets, tablets for oral suspension. Actelion Pharmaceuticals US, Inc (per FDA), South San Francisco, CA, 2017.
2. Bosentan. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated June 16, 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	Updated coverage duration to 12 months Removal of other criteria: Patient must not be using tobacco products.	All	7/1/2020