

Prior Authorization DRUG Guidelines

TRACLEER (bosentan)

Effective Date: 10/20/14

Date Developed: 10/14/14

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Description: TRACLEER is an endothelin receptor antagonist. Endothelin is a neurohormone which is elevated in the plasma and lung tissues of patients with pulmonary arterial hypertension (PAH).

Authorization Criteria: Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in patients with NYHA Class II, III, or IV symptoms to improve exercise capacity and decrease the rate of clinical deterioration.

Dosing: 62.5mg twice daily for 4 weeks then increase to 125mg twice daily

How Supplied: Tablets 62.6mg and 125mg

Contraindications/Warnings: An increase in liver aminotransferase levels may necessitate reduction in dosage, if greater than *8X the medication will most probably have to be discontinued; use lower doses if patient's weight is below 40kg (including pediatric patients); do not use with cyclosporine, glyburide, or if patient is pregnant; may decrease effectiveness of estrogenic contraceptives;

Major Adverse Reactions: Fluid retention; hepatotoxicity; pulmonary veno-occlusive disease; dose-related decrease in hemoglobin/hematocrit

Major Drug Interactions: Numerous interactions with C-P450, HMG-CoA Reductase and protease inhibiting agents (see product literature); reduces effectiveness of warfarins

REFERENCES

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2. Barst RJ, Ivy D, Dingemans J, et al, "Pharmacokinetics, Safety, and Efficacy of Bosentan in Pediatric Patients With Pulmonary Arterial Hypertension," *Clin Pharmacol Ther*, 2003, 73(4):372-82.
3. McLaughlin VV, Archer SL, Badesch DB, et al, "ACCF/AHA 2009 Expert Consensus Document on Pulmonary Hypertension: A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association: Developed in Collaboration

- with the American College of Chest Physicians, American Thoracic Society, Inc, and the Pulmonary Hypertension Association,” *J Am Coll Cardiol*, 2009, 53(11):1573-619.
4. Rosenzweig EB, Ivy DD, Widlitz A, et al, “Effects of Long-Term Bosentan in Children With Pulmonary Arterial Hypertension,” *J Am Coll Cardiol*, 2005, 46(4):697-704.
 5. Tracleer (bosentan) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals; October 2012.
 6. www.uptodate.com: Bosentan: Drug Guidelines

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