Orenitram (treprostinil)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Orenitram (treprostinil)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Orenitram (treprostinil) may be approved if the following criteria are met:

I. Individual has pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1][1]; **AND**
II. Individual has a right-heart catheterization showing all of the following (Hoeper, 2013; Ivy, 2013; Abman, 2015):
    A. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest;
    B. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg;
    C. Pulmonary vascular resistance (PVR) greater than 3 Wood units; **AND**
III. Individual has WHO functional class II-IV[2] symptoms.

Continuation requests for Orenitram (treprostinil) may be approved if the following criterion is met:

I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

Orenitram (treprostinil) may not be approved for the following:

I. Individual has a diagnosis of moderate (Child-Pugh Class B) or severe hepatic impairment (Child Pugh Class C); **OR**
II. In combination with other prostacyclin analogs [such as but not limited to epoprostenol (Flolan, Veletri), Ventavis (iloprost)] or prostacyclin receptor agonists [such as but not limited to Uptravi (selexipag)]; **OR**
III. In combination with other treprostinil dosage forms (subcutaneous, intravenous, inhalation), unless transitioning from one dose form to another.

Notes:

1. WHO Pulmonary Hypertension (PH) Group Classification (ACCF/AHA 2009, Simonneau et al. 2013):
    A. Group 1: Pulmonary arterial hypertension (PAH)
    B. Group 2: PH due to left heart disease
    C. Group 3: PH due to lung diseases and/or hypoxia
    D. Group 4: Chronic thromboembolic PH (CTEPH)
    E. Group 5: Miscellaneous/PH with unclear multifactorial mechanisms

2. WHO functional classification of PH (CHEST 2019):
    A. Class I: No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
    B. Class II: Slight limitation of physical activity. Comfortable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
    C. Class III: Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
    D. Class IV: Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.

Key References:

1. Abman SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society. *Circulation*. 2015; 132(21):2037-2099.
2. Badesch BD, Abman SH, Simonneau G, et al. Medical therapy for pulmonary arterial hypertension: updated ACCP evidence-based clinical practice guidelines. *Chest*. 2007; 131(6):1917-1928.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 15, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Hoeper MM, Bogaard HJ, Condliffe R, et al. Definitions and Diagnosis of Pulmonary Hypertension. *J Am Coll Cardiol*. 2013; 62(suppl 25):D42- D50. Available at: http://www.onlinejacc.org/content/62/25_Supplement/D42. Accessed: January 16, 2023.
6. Ivy DD, Abman SH, Barst RJ, et al. Pediatric Pulmonary Hypertension. *J Am Coll Cardiol*. 2013; 62(suppl 25):D117-D126. Available from: http://www.onlinejacc.org/content/62/25_Supplement/D117. Accessed: January 16, 2023.
7. Klinger JR, Elliott CG, Levine DJ, et. al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report. *CHEST*. 2019; 155(3): 565-586.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
9. 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. *J Am Coll Cardiol*. 2009; 53:1573-1619. Available at: http://circ.ahajournals.org/content/119/16/2250.full.pdf+html. Accessed: January 16, 2023.
10. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019; 53(1).

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.