

Market Applicability/Effective Date															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Orenitram (treprostinil)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Orenitram (treprostinil)

APPROVAL CRITERIA

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

- I. Individual has a catheterization-proven diagnosis² of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1]³; **AND**
- II. Individual has WHO functional class II-IV⁴ symptoms.

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. Orenitram (treprostinil) as the sole vasodilator has a small effect on exercise. Orenitram has not been shown to add benefit to other vasodilator therapy.
2. Diagnostic criteria:
 - A. PAH: Right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than 25 mm Hg; a pulmonary capillary wedge pressure (PCWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or

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- equal to 15 mm Hg; and a pulmonary vascular resistance (PVR) greater than 3 Wood units (ACCF/AHA 2009).
- B. CTEPH: Pulmonary angiography via right-heart catheterization which shows a mPAP greater than 25 mm Hg caused by thromboemboli in the pulmonary arterial system (ACCF/AHA 2009, Kim et al. 2013).
3. WHO Pulmonary Hypertension (PH) Group Classification (ACCF/AHA 2009, Simonneau et al. 2013):
- Group 1: Pulmonary arterial hypertension (PAH)
 - Group 2: PH due to left heart disease
 - Group 3: PH due to lung diseases and/or hypoxia
 - Group 4: Chronic thromboembolic PH (CTEPH)
 - Group 5: Miscellaneous/PH with unclear multifactorial mechanisms
4. WHO functional classification of PH (CHEST 2014):
- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
 - Class II: Slight limitation of physical activity. Comfortable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
 - 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.
 - 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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