Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Uptravi (selexipag)

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

Medications	Quantity Limit
Uptravi 200 mcg-800 mcg Titration Pack	May be subject to quantity limit
Uptravi 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg	

APPROVAL CRITERIA

Requests for Uptravi (selexipag) 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 the diagnosis of PAH confirmed by 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.

Uptravi (selexipag) may not be approved for the following:

I. Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C); **OR**
II. In combination with prostacyclin analogs [such as but not limited to treprostinil (Orenitram, Remodulin, Tyvaso), epoprostenol (Flolan, Veletri), Ventavis (iloprost)]; **OR**
III. Individual is on dialysis or a glomerular filtration rate less than 15 mL/min/1.73 m^2.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Notes:

1. WHO Pulmonary Hypertension (PH) Group Classification (ACCF/AHA 2009):
   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 2014):
   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.

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

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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 11, 2019.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. 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 11, 2019.
7. 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 11, 2019.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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 13, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

10. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic Therapy for Pulmonary Arterial Hypertension in Adults: CHEST Guideline and Expert Panel Report. *CHEST*. 2014; 146(2): 449-475. Available from: http://journal.publications.chestnet.org/data/Journals/CHEST/930614/chest_146_2_449.pdf. Accessed on: January 14, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.