

Market Applicability															
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

Sildenafil

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

Medications	Comments	Quantity Limit
Viagra (sildenafil)	Requests for Viagra in the treatment of Pulmonary Arterial Hypertension will be reviewed on a case by case basis.	May be subject to quantity limit
Revatio (sildenafil)	N/A	

APPROVAL CRITERIA

Requests for oral Revatio (sildenafil) 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;
- OR**
- III. Individual has a diagnosis of persistent pulmonary hypertension of the newborn (AHA/ATS 2015);
AND
 - IV. Individual was started and stabilized on Revatio (sildenafil) in the hospital and requires continued outpatient therapy.
 - V. Requests for Revatio (sildenafil) suspension may be approved if the following criteria are met in addition to I. and II. OR III. and IV. above:
 - A. Individual is unable to swallow the oral tablet dose form due to a clinical condition such as but not limited to the following:
 1. Dysphagia; **OR**
 2. Individual's age.

Requests for Revatio (sildenafil) injection may be approved if the following criteria are met:

- I. Individual has a catheterization-proven diagnosis² of PAH (WHO Group 1)³; **AND**
- II. Individual has WHO functional class II-IV⁴ symptoms; **AND**
- III. Individual is temporarily unable to take oral dose forms and requires continued therapy;

OR

- IV. Individual has a diagnosis of persistent pulmonary hypertension of the newborn (AHA/ATS 2015); **AND**
- V. Individual was started and stabilized on Revatio (sildenafil) in the hospital and requires continued outpatient therapy; **AND**
- VI. Individual is temporarily unable to take oral dose forms and requires continued therapy.

Revatio (sildenafil) oral and injectable agents may not be approved for the following:

- I. Individuals requesting for the treatment of erectile dysfunction; **OR**
- II. Individuals with severe hepatic impairment (Child-Pugh Class C); **OR**
- III. Individual has a diagnosis of pulmonary veno-occlusive disease (PVOD); **OR**
- IV. Individual has a known hereditary degenerative retinal disorder (such as but not limited to, retinitis pigmentosa); **OR**
- V. Use in combination with guanylate cyclase stimulators [such as but not limited to, Adempas (riociguat)]; **AND**
- VI. Use in combination with other phosphodiesterase-5 (PDE5) inhibitors [such as but not limited to, Viagra (sildenafil)]; **AND**
- VII. Use in combination with organic nitrates, such as but not limited to isosorbide mono/dinitrate or nitroglycerin.

Notes:

- 1. The addition of Revatio (sildenafil) to Tracleer (bosentan) therapy does not result in any beneficial effect on exercise ability (6-minute walk distance).
- 2. Diagnostic criteria for PAH (ACCF/AHA 2009): 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 equal to 15 mm Hg; and a pulmonary vascular resistance (PVR) greater than 3 Wood units.
- 3. 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
- 4. 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	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

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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 12, 2017.