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

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 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;

OR
IV. Individual has a diagnosis of persistent pulmonary hypertension of the newborn (Abman, 2015);
AND
V. Individual was started and stabilized on Revatio (sildenafil) in the hospital and requires continued outpatient therapy.

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

VI. Requests for Revatio (sildenafil) suspension may be approved if the following criteria are met in addition to I., II., and III. OR IV. and V. 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 pulmonary arterial hypertension (PAH) (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; **AND**
IV. Individual is temporarily unable to take oral dose forms and requires continued therapy;

OR

V. Individual has a diagnosis of persistent pulmonary hypertension of the newborn (Abman, 2015); **AND**
VI. Individual was started and stabilized on Revatio (sildenafil) in the hospital and requires continued outpatient therapy; **AND**
VII. 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**

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

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. 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 l: No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
    B. Class ll: Slight limitation of physical activity. Conformable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
    C. Class lll: 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 (AHA/ATS). 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 13, 2020.

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

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 17, 2020.
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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.; 2020; 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 15, 2020.
10. McVary KT, Roehrborn CG, Avins AN, et al. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH) Revised 2010. Reviewed and validity confirmed: 2014. Available from: http://www.auanet.org/education/clinical-practice-guidelines.cfm. Accessed on: March 11, 2020.

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.