

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

Adempas (riociguat)

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

Medications	Quantity Limit
Adempas (riociguat) 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Adempas (riociguat) 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 catheterization-proven diagnosis² of chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4)³; **AND**
- IV. Individual is using for one of the following:
 - A. Persistent or recurrent pulmonary hypertension after at least 180 days following surgical treatment with pulmonary endarterectomy; **OR**
 - B. Inoperable (via pulmonary endarterectomy) CTEPH;

AND

- V. Individual has WHO functional class II-IV⁴ symptoms.

Adempas (riociguat) may **not** be approved for the following:

- I. Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C); **OR**
- II. Individual is on dialysis or has a creatinine clearance less than 15 mL/min; **OR**
- III. Individual has a diagnosis of pulmonary veno-occlusive disease (PVOD); **OR**
- IV. Individual has a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP); **OR**
- V. Use in combination with phosphodiesterase (PDE) inhibitors [such as, PDE-5 inhibitors (sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (dipyridamole, theophylline)]; **OR**

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- VI. Use in combination with nitrates (such as but not limited to, nitroglycerin) or nitric oxide donors (such as but not limited to, amyl nitrite) in any form.

Notes:

1. Adempas (riociguat) has a black box warning for embryo-fetal toxicity. Pregnancy should be excluded prior to start of treatment, monthly during treatment, and 1 month after stopping treatment in females of reproductive potential. Adempas should not be administered to pregnant females due to the potential of causing fetal harm. Pregnancy should be prevented using acceptable means of contraception during treatment and for one month after therapy discontinued. Adempas will be available for all females, regardless of reproductive potential, through a restricted risk evaluation and mitigation strategy (REMS) program. As a component of the Adempas REMS, prescribers, individuals, and pharmacies must enroll in the program.
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 equal to 15 mm Hg; and a pulmonary vascular resistance (PVR) greater than 3 Wood units (ACCF/AHA 2009).
 - B. CTEPH (ACCF/AHA 2009, Kim et al. 2013): Pulmonary angiography via right-heart catheterization which shows a mPAP greater than 25 mm Hg caused by thromboemboli in the pulmonary arterial system.
3. 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
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.

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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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