ConnectiCare

Commercial/Healthcare Exchange PA Criteria
Effective: 5/11/2018

Prior Authorization: Adempas (riociguat)

Products Affected: Adempas (riociguat) oral tablets

Medication Description:

Riociguat stimulates soluble guanylate cyclase (sGC), which is the receptor for nitric oxide and an enzyme in the cardiopulmonary system. When nitric oxide binds to sGC, it catalyzes the synthesis of cyclic guanosine monophosphate (cGMP). Intracellular cGMP regulates processes that influence vascular tone, proliferation, fibrosis, and inflammation. Riociguat sensitizes sGC to endogenous nitric oxide by stabilizing nitric oxide-sGC binding and also by directly stimulates sGC via a different binding site. Riociguat stimulates the nitric oxide-sGC-cGMP pathway, which leads to increased generation of cGMP and subsequent vasodilation

Covered Uses:

1. Treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class.
2. Treatment of adults with pulmonary arterial hypertension (PAH), (WHO Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening.

Exclusion Criteria:

1. Pregnancy
2. Concomitant use with nitrates or nitric oxide donors (eg, amyl nitrate) in any form
3. Concomitant use with specific phosphodiesterase (PDE) 5 inhibitors (eg, sildenafil, tadalafil or vardenafil) or nonspecific PDE 5 inhibitors (eg, dipyridamole or theophylline)
4. Pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).

Required Medical Information:

1. Diagnosis
2. World Health Organization (WHO) functional class
3. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a pulmonologist or a cardiologist

Coverage Duration: 12 months

Other Criteria:

Chronic-Thromboembolic Pulmonary Hypertension

A. Patient has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)), (WHO Group 4); **AND**
B. Patient has had surgical intervention or has inoperable CTEPH.

Pulmonary Arterial Hypertension

A. Patient has a diagnosis of pulmonary arterial hypertension (PAH), (WHO Group 1); **AND**
B. Patient has tried and failed or has a contraindication or intolerance to sildenafil 20mg oral tablets.

References:

1. Product Information: ADEMPAS oral tablets, riociguat oral tablets. Bayer HealthCare Pharmaceuticals Inc. (per FDA), Whippany, NJ, 2017.
2. Riociguat. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated April 21, 2020. Accessed June 18, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/11/2018
2	Annual Review	No Changes; CCI adopted EH policy and template	All	01/14/2020
3	Revision	Removal from CCI PAH Policy Renamed Adempas policy Coverage duration updated to 12 months Removal of other criteria: In both indications patient must not be using tobacco products.	All	7/1/2020