MEDICAL MUTUAL®

Drug Policy

Policy:	Adempas (riociguat)	Annual Review Date: 2/20/2025 Last Revised Date: 2/20/2025

OVERVIEW

Adempas, a soluble guanylate cyclase stimulator, is indicated for the treatment of adults with:

- **Chronic thromboembolic pulmonary hypertension** (CTEPH) [World Health Organization {WHO} Group 4], persistent/recurrent, after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class.
- **Pulmonary Arterial Hypertension** (PAH) [WHO Group 1], to improve exercise capacity, WHO functional class, and to delay clinical worsening.

POLICY STATEMENT

This policy involves the use of Adempas. Prior authorization is recommended for pharmacy benefit coverage of Adempas. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Adempas as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Adempas be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Adempas is recommended in those who meet the following criteria:

1. **Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets all of the following (i, ii, and iii):
     - **i.** Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
     - **ii.** Patient meets the following (a and b):
       - **a)** Patient has had a right heart catheterization*; AND
       - **b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND

iii. Medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

B) Patient is Currently Receiving Adempas. Approve for 1 year if the patient meets all of the following (i ii, and iii):
- **i.** Patient has a diagnosis of WHO Group 1 PAH; AND
- **ii.** Patient meets the following (a and b):
  - **a)** Patient has had a right heart catheterization; AND
  - **b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
- **iii.** Medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

1. Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Criteria. *Patient must meet the following criteria (A, B, and C):*

A. Persistent/recurrent CTEPH (WHO Group 4); AND
B. The patient has been treated surgically, or CTEPH is inoperable; AND
C. Adempas is prescribed by or in consultation with a cardiologist or pulmonologist

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Adempas has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.** Use of Adempas with phosphodiesterase inhibitors and/or with other soluble guanylate cyclase stimulators is a contraindication.[1]
   Note: Examples of phosphodiesterase inhibitors used for pulmonary hypertension include Revatio (sildenafil tablets, suspension, and intravenous injection), Adcirca (tadalafil tablets), Alyq (tadalafil tablets), Tadliq (tadalafil oral suspension) and Opsynvi (macitentan/tadaladil tablets). An example of a soluble guanylate cyclase stimulator is Verquvo (vericiguat tablets).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Adempas® tablets [prescribing information]. Whippany, NJ: Bayer; February 2017.
2. McLaughlin VV, Archer SL, Badesch DB, et all; Writing committee members. 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: Developed in collaboration with the American College of Chest Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. *Circulation*. 2009;119:2250-2294.
3. McGoon M, Gutterman D, Steen V, et al. Screening, early detection, and diagnosis of pulmonary arterial hypertension: ACCP evidence-based clinical practice guidelines. *CHEST*. 2004;126:14-34.
4. Badesch, Abman SH, Simonneau G, et al. Medical therapy for pulmonary arterial hypertension. Updated ACCP Evidence-based clinical practice guidelines. *CHEST*. 2007;131:1917-1928.
5. Simonneau G, Gatzoulis MA, Adatia I, et al. Updated clinical classification of pulmonary hypertension. *J Am Coll Cardiol*. 2013;62(25 Suppl):D34-D41.
6. Hoeper MM, Madani MM, Nakanishi N, et al. Chronic thromboembolic pulmonary hypertension. *Lancet Respir Med*. 2014;2(7):573-582.
7. Kim NH. Group 4 pulmonary hypertension. Chronic thromboembolic pulmonary hypertension: epidemiology, pathophysiology and treatment. *Cardiol Clin*. 2016;34:435-441.
8. Riocigual. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 2 January 2019. Accessed on 20 February 2019.