Policy Name:	Adempas (riociguat)	Policy #:	2313P

Purpose of the Policy

The purpose of this policy is to establish prior authorization criteria for Adempas.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Adempas under the specialty pharmacy benefit when the criteria below have been met.

Criteria

1. Coverage Criteria for Pulmonary Arterial Hypertension

1.1   See Pulmonary Arterial Hypertension Products policy

2. Coverage Criteria for Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

2.1   Diagnosis of CTEPH

2.2   Age 18 years or older

2.3   Prescribed by or in consultation with a pulmonologist (lung doctor) or cardiologist (heart doctor)

2.4   Disease is inoperable or persistent/recurrent after surgical treatment

3. Exclusion Criteria

3.1   Patients with severe liver disease, creatinine clearance <15mL/min or on dialysis.

3.2   Pregnant patients

3.3   Co-administration with nitrates or nitric oxide donors (nitroglycerin, isosorbide mononitrate, isosorbide dinitrate)

3.4   Concomitant administration with phosphodiesterase (PDE) inhibitors such as sildenafil or tadalafil

4. Approval Period

4.1   Initial: 12 months

4.2   Reauthorization: 12 months with documented clinical benefit on therapy

References

1. Adempas [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; September 2021.
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3. 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 developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009;53(17):1573-1619.
4. Delcroix M, Torbicki A, Gopalan D, et al. ERS statement on chronic thromboembolic pulmonary hypertension. Eur Respir J. 2021 Jun 17;57(6):2002828.
5. Ghofrani HA, D'Armini AM, Grimminger F, et al. Riociguat for the treatment of chronic thromboembolic pulmonary hypertension. New Engl J Med. 2013;369(4):319-329.

Created Date: 01/14/14
Effective Date: 02/05/14
Posted to Website: 01/01/22
Revision Date: 06/05/24