

PRIOR AUTHORIZATION POLICY

POLICY: Pulmonary Arterial Hypertension – Adempas Prior Authorization Policy

- Adempas® (riociguat tablets – Bayer)

REVIEW DATE: 10/9/2024

OVERVIEW

Adempas, a soluble guanylate cyclase stimulator, is indicated for the treatment of adults with:¹

- **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.

Disease Overview

PAH is a serious but rare condition impacting fewer than 20,000 patients in the US.^{2,3} It is classified within Group 1 pulmonary hypertension among the five different groups that are recognized. In this progressive disorder, the small arteries in the lungs become narrowed, restricted, or blocked causing the heart to work harder to pump blood, leading to activity impairment.^{2,3} Although the mean age of diagnosis is between 36 and 50 years, patients of any age may be affected, including pediatric patients. PAH is defined as a mean pulmonary artery pressure (mPAP) > 20 mmHg (at rest) with a pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg and a pulmonary vascular resistance > 2 Wood units measured by cardiac catheterization.⁷ The prognosis in PAH has been described as poor, with the median survival being approximately 3 years. However, primarily due to advances in pharmacological therapies, the long-term prognosis has improved.

CTEPH is a persistent obstruction of pulmonary arteries and is often a complication of pulmonary embolism.^{4,5} It is classified within WHO Group 4 pulmonary hypertension. Symptoms include progressive dyspnea on exertion, as well as fatigue, syncope, hemoptysis, and signs of right heart failure. Pulmonary endarterectomy is the treatment of choice for most patients with CTEPH. However, around 40% of patients are deemed inoperable for various reasons. Medication therapy, including Adempas, may also be recommended. Anticoagulant therapy is also given.

Guidelines

Various guidelines are available for the management of pulmonary hypertension.

- **Pulmonary Arterial Hypertension:** The CHEST guideline and Expert Panel Report regarding therapy for PAH in adults (2019) cites Adempas as a vital therapy with several benefits in a variety of clinical scenarios. The European Society of Cardiology (ESC) and the European Respiratory Society (ERS) guidelines regarding the treatment of pulmonary hypertension (2022) also recognize Adempas as having a prominent role in the management of this condition, as monotherapy or in combination with other agents.
- **Chronic Thromboembolic Pulmonary Hypertension:** Guidelines from the ESC/ERS regarding the treatment of pulmonary hypertension (2022) recommended Adempas for patients who are symptomatic with inoperable CTEPH or persistent/recurrent pulmonary hypertension after pulmonary endarterectomy.⁶

POLICY STATEMENT

10/11/2023

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Prior Authorization is recommended for prescription benefit coverage of Adempas. All approvals are provided for the duration noted below. 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, approval requires Adempas to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required for initiation of therapy where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes and catheterization laboratory reports. For a patient case in which the documentation requirement of the right heart catheterization upon Prior Authorization coverage review for a different medication indicated for WHO Group 1 PAH has been previously provided, the documentation requirement in this *Pulmonary Arterial Hypertension – Adempas Prior Authorization Policy* is considered to be met.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Chronic Thromboembolic Pulmonary Hypertension.** Approve for 1 year if prescribed by or in consultation with a pulmonologist or a cardiologist.
2. **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 BOTH of the following (a and b):
 - a) Patient has had a right heart catheterization **[documentation required]** (see documentation section above); 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 World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
 - ii. Patient meets BOTH of the following (a and b):
 - a) Patient has had a right heart catheterization; AND
Note: This refers to prior to starting therapy with a medication for WHO Group 1 PAH.
 - 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Adempas is not recommended in the following situations:

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.

REFERENCES

1. Adempas® tablets [prescribing information]. Whippany, NJ: Bayer; January 2023.
2. Ruopp NF, Cockrill BA. Diagnosis and treatment of pulmonary arterial hypertension. A review. *JAMA*. 2022;327(14):1379-1391.
3. 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.
4. Kim NH, Delcroix M, Jais X, et al. Chronic thromboembolic pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801915.
5. Papamatheakis DG, Poch DS, Fernandes TM, et al. Chronic thromboembolic pulmonary hypertension: JACC focus seminar. *J Am Coll Cardiol*. 2020;76(180):2155-2169.
6. Humbert M, Kovacs G, Hoeper MM, et al, for the ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022;43(38):3618-3731.
7. Maron BA. Revised Definition of Pulmonary Hypertension and Approach to Management: A Clinical Primer. *J Am Heart Assoc*. 2023 Apr 18;12(8):e029024. [Epub].