Drug Quantity Management – Per Rx
Pulmonary Arterial Hypertension – Adempas® (riociguat tablets)

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Product Identifier(s)

Effective 1/1/23 to 4/11/23: 111217

Effective 4/12/23: 108693

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Adempas. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Adempas® (riociguat tablets)	0.5 mg tablets	90 tablets	270 tablets
	1 mg tablets	90 tablets	270 tablets
	1.5 mg tablets	90 tablets	270 tablets
	2 mg tablets	90 tablets	270 tablets
	2.5 mg tablets	90 tablets	270 tablets

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Adempas tablets (all strengths)

1. If the individual is a smoker, approve a quantity sufficient for a 30-day supply at retail and a 90-day supply at home delivery.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Adempas, a soluble guanylate cyclase (sGC) 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.

Dosing

The recommended starting dose of Adempas is 1 mg three times daily (TID).[1] If a patient may not tolerate the hypotensive effect of Adempas, consider a starting dose of 0.5 mg TID. If the patient's systolic blood pressure remains > 95 mmHg and the patient has no signs or symptoms of hypotension, up-titrate the dose by 0.5 mg taken TID. Dose increases should occur not more frequently than every 2 weeks. The dose may be increased to the highest tolerated dose, up to a maximum of 2.5 mg TID. If at any time, the patient has symptoms of hypotension, decrease the dose by 0.5 mg TID. Tablets may be crushed and mixed with water or soft foods prior to administration for a patient who is unable to swallow whole tablets.

If a dose is missed, the patient should continue with the next regularly scheduled dose.[1] If Adempas therapy is interrupted for ≥ 3 days, re-titrate with Adempas. In patients who smoke, consider titrating the dose higher than 2.5 mg TID, as plasma concentrations of Adempas are reduced by 50% to 60% compared with non-smokers. A lower starting dose of 0.5 mg TID may be necessary to manage drug interactions.

Availability

Adempas is available as 0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg tablets in bottles containing 9 or 90 tablets.[1]

References

1. Adempas® tablets [prescribing information]. Whippany, NJ: Bayer; September 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
New Policy	--	08/10/2022