

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Pulmonary Arterial Hypertension – Adempas Drug Quantity Management Policy – Per Rx

- Adempas® (riociguat tablets – Bayer)

REVIEW DATE: 08/10/2022

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

POLICY STATEMENT

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.

Automation: None.

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

Adempas tablets (all strengths)

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

REFERENCES

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