Adempas®
riociguat tablets
0.5mg | 1mg | 1.5mg | 2mg | 2.5mg

# Submitting a Letter of Medical Necessity for Adempas® (riociguat)

## AETNA® MEDICARE ADVANTAGE AND SILVERSCRIPT® PLANS/ CVS CAREMARK®

## INDICATIONS

- Adempas (riociguat) is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class.
- Adempas is indicated for the treatment of adults with pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening.*

Efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO functional class II–III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%).

*Time to clinical worsening was a combined endpoint defined as death (all-cause mortality), heart/lung transplantation, atrial septostomy, hospitalization due to persistent worsening of pulmonary hypertension, start of new PAH-specific treatment, persistent decrease in 6MWD, and persistent worsening of WHO functional class.

## IMPORTANT SAFETY INFORMATION

**WARNING: EMBRYO-FETAL TOXICITY**

**Adempas is contraindicated for use during pregnancy because it may cause fetal harm based on animal data.**

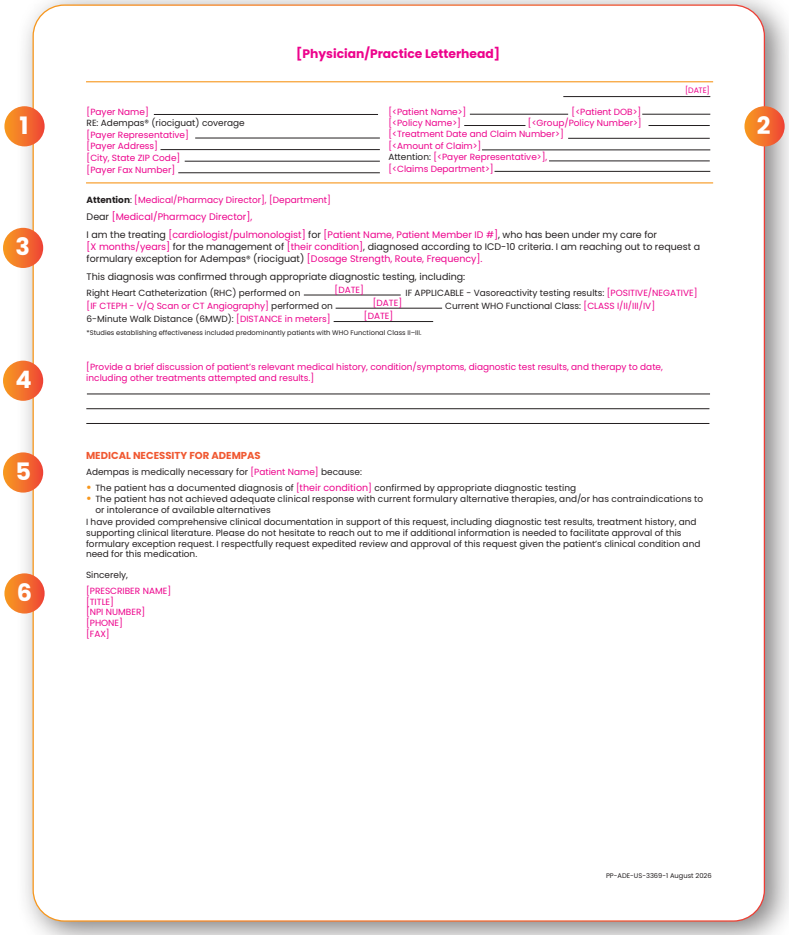
**Exclude pregnancy prior to the start of treatment with Adempas. Advise use of effective contraception prior to initiation of treatment, during treatment, and for one month after treatment with Adempas.**

**If pregnancy is detected, discontinue Adempas as soon as possible.**

**Please see additional Important Safety Information, including Boxed Warning, throughout, and accompanying full Prescribing Information.**

**Aetna, SilverScript, and CVS Caremark are subsidiaries of CVS Health.**

# This resource can help keep your patients on the brand of medicine they're familiar with



[Physician/Practice Letterhead]

[DATE]

1

[Payer Name] _____
RE: Adempas® (riociguat) coverage
[Payer Representative] _____
[Payer Address] _____
[City, State ZIP Code] _____
[Payer Fax Number] _____

2

[<Patient Name>] _____ [<Patient DOB>] _____
[<Policy Name>] _____ [<Group/Policy Number>] _____
[<Treatment Date and Claim Number>] _____
[<Amount of Claim>] _____
Attention: [<Payer Representative>], _____
[<Claims Department>] _____

**Attention**: [Medical/Pharmacy Director], [Department]

Dear [Medical/Pharmacy Director],

3

I am the treating [cardiologist/pulmonologist] for [Patient Name, Patient Member ID #], who has been under my care for [X months/years] for the management of [their condition], diagnosed according to ICD-10 criteria. I am reaching out to request a formulary exception for Adempas® (riociguat) [Dosage Strength, Route, Frequency].

This diagnosis was confirmed through appropriate diagnostic testing, including:

Right Heart Catheterization (RHC) performed on _____[DATE]_____ IF APPLICABLE - Vasoreactivity testing results: [POSITIVE/NEGATIVE]
[IF CTEPH - V/Q Scan or CT Angiography] performed on _____[DATE]_____. Current WHO Functional Class: [CLASS I/II/III/IV]
6-Minute Walk Distance (6MWD): [DISTANCE in meters] _____[DATE]_____

*Studies establishing effectiveness included predominantly patients with WHO Functional Class II–III.

4

[Provide a brief discussion of patient's relevant medical history, condition/symptoms, diagnostic test results, and therapy to date, including other treatments attempted and results.]

5

**MEDICAL NECESSITY FOR ADEMPAS**

Adempas is medically necessary for [Patient Name] because:

- The patient has a documented diagnosis of [their condition] confirmed by appropriate diagnostic testing
- The patient has not achieved adequate clinical response with current formulary alternative therapies, and/or has contraindications to or intolerance of available alternatives

I have provided comprehensive clinical documentation in support of this request, including diagnostic test results, treatment history, and supporting clinical literature. Please do not hesitate to reach out to me if additional information is needed to facilitate approval of this formulary exception request. I respectfully request expedited review and approval of this request given the patient's clinical condition and need for this medication.

6

Sincerely,

[PRESCRIBER NAME]
[TITLE]
[NPI NUMBER]
[PHONE]
[FAX]

PP-ADE-US-3369-1 August 2026

## IMPORTANT SAFETY INFORMATION (continued)

### CONTRAINDICATIONS

- Use of Adempas is contraindicated in patients who are pregnant.
- Co-administration of Adempas with nitrates or nitric oxide donors (such as amyl nitrite) in any form is contraindicated.
- Concomitant administration of Adempas with specific phosphodiesterase (PDE)-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or nonspecific PDE inhibitors (such as dipyridamole or theophylline) is contraindicated. Do not administer within 24 hours of sildenafil. Do not administer 24 hours before or within 48 hours after tadalafil.

### CONTRAINDICATIONS (continued)

- Adempas is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators.
- Adempas in contraindicated in patients with Pulmonary Hypertension associated with Idiopathic Interstitial Pneumonias (PH-IIP).

**Please see additional Important Safety Information, including Boxed Warning, throughout, and accompanying full Prescribing Information.**

# Filling out your Letter of Medical Necessity

**If Adempas® (riociguat) is not included on a health plan's list of covered drugs and a patient's claim has been denied, providers may submit a Letter of Appeal for their patients. It is important to provide complete and accurate information in the letter to aid in the reassessment of the denial. Please see below for additional details that the payer may require in order to approve coverage for Adempas.**

1. **Address payer accurately.**
2. **Provide all Patient Information,** including Patient Pharmacy Member ID #.
3. **Include all details related to medication strength, quantity, dosage form, route of administration, and frequency**.

   **If the patient is new to Adempas**, include relevant details and directions for the initial dose and the titration schedule. **Enter appropriate and specific ICD-10-CM code(s).**

4. **Detail all relevant patient medical history**, including:

   **a)** Documented diagnosis

   **b) Key diagnostic test values**

   **c) Treatment history** specific to the diagnosis, including medication dosage regimens, start/stop dates, and responses to treatment

5. **Attach copies of all relevant supporting documents**, which may include: diagnostic reports, treatment notes, clinical practice guidelines, clinical trial publications, and the Prescribing Information for Adempas.
6. **Provide your practice contact information to ensure Payer Organization can reach you with follow-up questions**.

*This resource is for informational purposes only and does not guarantee that coverage will result.*

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS

**Embryo-Fetal Toxicity.** Based on data from animal reproduction studies, Adempas may cause fetal harm when administered to a pregnant patient and is contraindicated during pregnancy. The available human data for riociguat do not establish the presence or absence of major birth defects related to the use of Adempas. Counsel patients who can become pregnant on the potential risk to a fetus. Exclude pregnancy prior to initiation of treatment with Adempas. Advise females of reproductive potential to use effective contraception prior to initiation of treatment, during treatment with Adempas and for at least one month after the last dose. When pregnancy is detected, discontinue Adempas as soon as possible.

**Hypotension.** Adempas reduces blood pressure. Consider the potential for symptomatic hypotension or ischemia in patients with hypovolemia, severe left ventricular outflow obstruction, resting hypotension, autonomic dysfunction, or concomitant treatment with antihypertensives or strong CYP and P-gp/BCRP inhibitors. Consider a dose reduction if patient develops signs or symptoms of hypotension.

**Please see additional Important Safety Information, including Boxed Warning, throughout, and accompanying full Prescribing Information.**

# Bayer is committed to providing you and your patients with the tools you need to continue Adempas treatment every step of the way

**If you need further assistance following submitting this letter, please contact the respective Specialty Pharmacy (SP) or Aim Support at 1-855-4ADEMPAS (1-855-423-3672).**

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

**Bleeding.** In the placebo-controlled clinical trials, serious bleeding occurred in 2.4% of patients taking Adempas compared to 0% of placebo patients. Serious hemoptysis occurred in 5 (1%) patients taking Adempas compared to 0 placebo patients, including one event with fatal outcome. Serious hemorrhagic events also included 2 patients with vaginal hemorrhage, 2 with catheter-site hemorrhage, and 1 each with subdural hematoma, hematemesis, and intra-abdominal hemorrhage.

**Pulmonary Veno-Occlusive Disease.** Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD). Therefore, administration of Adempas to such patients is not recommended. Should signs of pulmonary edema occur, the possibility of associated PVOD should be considered and if confirmed, discontinue treatment with Adempas.

### MOST COMMON ADVERSE REACTIONS

The most common adverse reactions occurring more frequently (≥3%) on Adempas than placebo were headache (27% vs 18%), dyspepsia/gastritis (21% vs 8%), dizziness (20% vs 13%), nausea (14% vs 11%), diarrhea (12% vs 8%), hypotension (10% vs 4%), vomiting (10% vs 7%), anemia (7% vs 2%), gastroesophageal reflux disease (5% vs 2%), and constipation (5% vs 1%).

Other events that were seen more frequently in Adempas compared to placebo and potentially related to treatment were palpitations, nasal congestion, epistaxis, dysphagia, abdominal distension, and peripheral edema.

**Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning.**

BAYER, the Bayer Cross, and Adempas are registered trademarks of Bayer.

BAYER 100 Bayer Boulevard, Whippany, NJ 07981 USA
© 2026 Bayer PP-ADE-US-3370-1 August 2026