Adempas® (riociguat) Prescription and Patient Support Program Enrollment Form for VA Patients

Complete this form which is available at www.adempas-us.com. Prescribers and all female patients must be enrolled in the Adempas REMS Program prior to initiating treatment. Please visit www.AdempasREMS.com to access the Adempas REMS materials including the Adempas REMS Patient Enrollment and Consent Form. Forward this completed form to the VA Pharmacy who will then fax the form to the Adempas Program at 1-855-662-5200.

SECTION 1 Contact Information

By providing an email or phone, the patient agrees to receive automated calls, texts and/or email messages from myAIM Program administrator and the patient's pharmacy (CVS Specialty or Accredo) about your prescription and healthcare. Consent may be revoked at any time and is not a condition of the service. Carrier message and data rates may apply.

Patient Contact Information (*indicates required field)

Patient First Name*:		Patient Last Name*:		Birthdate* (MM/DD/YYYY):	Sex*: ☐ Male ☐ Female
Address*:	City*:	State*:	Zip Code*:	Preferred Phone*:	*OK to leave detailed message?* ☐ Yes ☐ No
Email:			Preferred Language: ☐ English ☐ Spanish ☐ Other (specify) _____		
Alternate Contact Name:		Alternate Contact Phone:		Relationship to Patient:	

Prescriber Contact Information (*indicates required field)

Prescriber First Name*:	Prescriber Last Name*:			NPI*:
Address Line 1*:	Address Line 2:	City:	State:	Zip Code:
Office Contact:	Phone:	Fax:		

SECTION 2 Prescription

Paitent Diagnosis Information (*indicates required field)

Please check one ICD-10 Code*:

Pulmonary arterial hypertension
- ☐ I27.0
- ☐ I27.21

Chronic thromboembolic pulmonary hypertension
- ☐ I27.24
  - ☐ Inoperable
  - ☐ Persistent/Recurrent

☐ **OTHER (please specify)**
_____
_____
_____

Therapy Status:
- ☐ Initial therapy (monotherapy or in combination)
- ☐ Add-on therapy
- ☐ Transition from other therapy

Prescription (*indicates required field)

Note: NY Prescribers please submit prescription on an original NY State prescriptions blank. For all other States, send on a State-specific prescription blank if applicable for your State.

Starting dose*:

☐ **Adempas 1 mg tablet by mouth three times a day**

☐ Adempas 0.5 mg tablet by mouth three times a day

Quantity:
☐ 30 day supply

Refills:_____

Titration schedule:

Please check box for all dosages to be incorporated:

☐ Based on patient's response per clinical evaluation of the physician or the nurse in consultation with the physician, the pharmacy is to provide the Adempas strength to accommodate titration needs of therapy.

Adempas Tablets: 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg

Directions: If systolic blood pressure is >95 mmHg and there are no signs/symptoms of hypotension, up titrate by 0.5 mg 3 times per day at intervals no sooner than 2 weeks to the highest tolerated dosage up to a maximum of 2.5 mg 3 times per day. If at any time, the patient has symptoms of hypotension, decrease the dosage by 0.5 mg 3 times daily. The established individual dose should be maintained.

Other special instructions: _____

Quantity: ☐ 30 day supply Refills:_____

I certify that the above information provided is accurate to the best of my knowledge. I appoint the Adempas AIM Program, on my behalf, to convey this prescription to the dispensing pharmacy. I understand that I may not delegate signature authority.

PRESCRIBER SIGNATURE REQUIRED

Dispense as Written*:	**Date*:**
Substitutions Permitted*:	**Date*:**

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PP-ADE-US-3214-1
February 2025

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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

Do not administer Adempas (riociguat) tablets to a pregnant female because it may cause fetal harm.

Females of reproductive potential: Exclude pregnancy before the start of treatment, monthly during treatment, and one month after stopping treatment. To prevent pregnancy, females of reproductive potential must use effective forms of contraception during treatment and for one month after stopping treatment.

For all female patients, Adempas is available only through a restricted program called the Adempas Risk Evaluation and Mitigation Strategy (REMS) Program.

CONTRAINDICATIONS

Adempas is contraindicated in:

- Pregnancy. Based on data from animal reproduction studies, Adempas may cause fetal harm when administered to a pregnant woman and is contraindicated in females who are pregnant. Adempas was consistently shown to have teratogenic effects when administered to animals. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.
- Co-administration with nitrates or nitric oxide donors (such as amyl nitrite) in any form.
- Concomitant administration 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.
- Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators.
- Patients with Pulmonary Hypertension associated with Idiopathic Interstitial Pneumonias (PH-IIP).

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity. Based on data from animal reproduction studies, Adempas may cause embryo-fetal toxicity when administered to a pregnant female and is contraindicated in females who are pregnant. Advise females of reproductive potential of the potential risk to a fetus. Obtain a pregnancy test before the start of treatment, monthly during treatment, and for one month after stopping treatment. Advise females of reproductive potential to use effective contraception during treatment with Adempas and for at least one month after the last dose.

For females, Adempas is only available through a restricted program under the Adempas REMS Program.

Adempas REMS Program. Females can only receive Adempas through the Adempas REMS Program, a restricted distribution program.

Important requirements of the Adempas REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- All females, regardless of reproductive potential, must enroll in the Adempas REMS Program prior to initiating Adempas. Male patients are not enrolled in the Adempas REMS Program.
- Female patients of reproductive potential must comply with the pregnancy testing and contraception requirements.
- Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive Adempas.

Further information, including a list of certified pharmacies, is available at www.AdempasREMS.com or 1-855-4ADEMPAS.

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.

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.

For important risk and use information, please click here to see the full Prescribing Information, including Boxed Warning.

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February 2025

Phone: 1-855-4ADEMPAS (1-855-423-3672) | www.adempasREMS.com

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SECTION 3 Delivery and VA Pharmacy Information

Delivery Information (check one)

Deliver to: ☐ Patient Home ☐ VA Pharmacy (address listed below)

VA Pharmacy Information (‡indicates required field)

VA Pharmacy Name‡: _____

Dept.‡: _____ Attn.‡: _____

Address Line 1‡: _____ Address Line 2‡: _____

City‡: _____ State‡: _____ Zip‡: _____

Phone‡: _____ Fax‡: _____

Purchase Order #‡: _____ Effective Date‡: _____ Expiration Date‡: _____

Method of Payment‡: ☐ Credit Card: Call Pharmacy Contact ☐ E-Invoice Tungsten Network

Primary Clinical Contact‡

Name: _____ Phone: _____

Fax: _____ E-mail: _____

Secondary Clinical Contact

Name: _____ Phone: _____

Fax: _____ E-mail: _____

Primary Purchasing Contact‡

Name: _____ Phone: _____

Fax: _____ E-mail: _____

Secondary Purchasing Contact

Name: _____ Phone: _____

Fax: _____ E-mail: _____

NOTE: Incomplete mandatory fields will lead to a delay in processing

‡Indicates required fields for Specialty Pharmacy

Accredo Health Group Inc. • 866.344.4874

Hours: Monday – Friday, 8:00 a.m. to 8:00 p.m. ET

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SECTION 4 Patient Support Program Enrollment

Patient Support Program Enrollment

Bayer offers patient support services for Adempas patients that include: (A) nurses to support you in starting therapy and achieving your optimal dose and (B) education about CTEPH and/or PAH as well as helpful tips for managing your Adempas therapy ("myAIM"). These Programs are entirely optional and you may enroll in one or all of these Programs, which are not a part of, endorsed by, or administered by the US Department of Veteran Affairs. To enroll in myAIM, you will need to sign a HIPAA authorization in order for your healthcare provider and/or pharmacy to share your protected healthcare information with Bayer and the myAIM Program administrator.

You will remain enrolled in each Program that you select unless you opt-out either by contacting myAIM via telephone at 1-855-423-3672 or by written notification sent to: 200 Pinecrest Plaza, Morgantown WV 26505, or until your HIPAA Authorization expires. These services are not a part of endorsed by or administered by the U.S. Department of Veterans Affairs.

Please enroll me in: (check all that apply) ☐ A: Nursing ☐ B: Benefits Verification and Financial Assistance

☐ C: Digital Educational Information – e-mail address: _____@_____

Patient – please initial here to confirm your optional elections: _____ **These services are provided at no charge.**

Patient can opt-out of any one of the above programs (or all) by contacting the AIM program.

Please contact the AIM program directly at 1-855-4ADEMPAS to opt-out of any patient support program.

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PATIENT HIPAA AUTHORIZATION

NOTE: This authorization applies only if the patient is opting in to the Aim Patient Support Program.

If you DO NOT wish to enroll in the Aim Patient Support Program, please check the "I Decline" box below and initial.

☐ **I accept. Patient initials:** _____ ☐ **I decline. Patient initials:** _____

I voluntarily provide this authorization for the use and disclosure of my Protected Health Information ("PHI"), as such term is defined by the Health Insurance Portability and Accountability Act of 1996 (as amended, "HIPAA"). I understand that PHI is health information that identifies me or that could reasonably be used to identify me.

I authorize my healthcare provider, including my physician and pharmacy, and my health plan, to disclose to Bayer and its contracted agents my name, address, telephone number, health insurance status and coverage and such medical information as may be necessary for me to enroll in the Aim Patient Support Program. I understand this disclosure(s) will contain PHI, including information about my current medical condition, treatment, coordination of treatment and receipt of medication. I allow the use and disclosure of my PHI to Bayer its contracted agents for the following purposes:

- To verify my insurance information and coverage
- To ensure the accuracy and completeness of the the Aim Patient Support Program Enrollment Form
- To provide education, training, and ongoing support on the use of my Bayer medication
- To send me information on Bayer products and services related to my treatment
- To send me refill reminders for my Bayer prescription medication and to encourage its appropriate use
- To communicate with me, my healthcare providers and health plan about my medical care and treatment
- To contact me for market research feedback, and as necessary to comply with applicable laws
- Bayer may contact me for potential adverse event follow up

I understand that:

- This Authorization will remain in effect until the end of my participation in the Aim Patient Support Program or 10 years, unless subject to applicable law from the date of my signature on this Authorization, whichever occurs later.
- I may cancel this Authorization at any time by contacting myAim via telephone at 1-855-423-3672.
- If I cancel this Authorization my healthcare provider and health plan will stop sharing my PHI with Bayer and its contracted agents. However, the revocation will not affect prior use or disclosure of my PHI in reliance on this Authorization.
- That entities that receive my PHI in accordance with this Authorization may not be required by law to keep the information private and that it will no longer be protected by the HIPAA privacy law. It may become available in the public domain.
- I do not need to sign this Authorization to receive medical treatment or medication. However, if I do not sign this Authorization, I may not participate in the Aim Patient Support Program or be eligible for other Bayer patient support programs.
- My healthcare providers, insurers, and health plans may receive remuneration (payment) from Bayer in exchange for providing services to Bayer that may involve use or disclosure of my PHI.

I have read and understand the terms of this Authorization and have had the opportunity to ask questions about the uses and disclosures of PHI. I understand that I am entitled to receive a signed copy of this authorization and can get more information about the use and disclosure of PHI by contacting the Aim Patient Support Program at 1-855-4ADEMPAS (1-855-423-3672).

PATIENT TO SIGN AND DATE

SIGNATURE REQUIRED ONLY IF PATIENT IS OPTING IN.

Patient Name (print): _____

Patient (or legal guardian) Signature*: _____ **Date (mm/dd/yyyy):** _____

If signed by a legal representative —

Print Name: _____ **Relationship to patient:** _____

For important risk and use information, please see the accompanying full Prescribing Information, including Boxed Warning.

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