Instructions for completing the Prescription and Patient Support Program Enrollment Form



		ntact Infor	mation	Program adm Consent may	inistrator and the patient's be revoked at any time an	pharmacy (CVS Sp d is not a condition	ecialty or Accredo) a of the service. Carrie	bout your prescription and heal r message and data rates may a	m myAIM Ithcare. apply.	At least 1
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Relationship to patient: _

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

Complete this form which is available at <u>www.adempas-us.com</u>. Prescribers and all female patients must be enrolled in the Adempas REMS Program prior to initiating treatment. Please visit <u>www.AdempasREMS.com</u> to access the Adempas REMS materials including the *Adempas REMS Patient Enrollment and Consent Form*, and fax them along with patient insurance information to the Adempas Program at 1-855-662-5200 or send electronically by visiting <u>www.adempasREMS.com</u>.

SECTION 🚺 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 (* indicat	es required	field)								
Patient		Patient				Birthdate*			Gender*:	
First Name*:		Last Name*:				(MM/DD/YYYY):			Male Female	
Address*:	City*:		State*:	Zip	Preferr	ed		OK to	leave detailed	
				Code*:	Phone	*:		messa	age? Yes No	
Email:			Preferred	Language:						
	@		Englis	sh 🗌 Spanish	Other	(specify)				
Alternate		Alternate	Alternate Relationship							
Contact Name:		Contact Phone: to Patie					Patient:			
Prescriber Contact Information (* ind	icates requii	red field)								
Prescriber		Prescriber					N	PI*:		
First Name*:		Last Name*:								
Address		Address			City:		State:	Zi		
Line 1*:		Line 2:						Co	ode:	
Office Pho		Phone:			Fax:					
Contact:										

SECTION 2 Patient Information

Patient Information (* indicates required field)	
Is Patient starting Adempas in a hospital setting? Yes No Start Date:	Discharge Date:
Does the patient have prescription coverage*? Yes No	
Patient's local pharmacy:	Phone:
PROVIDE ALL PATIENT INSURANCE INFORMATION, INCLUDING DR Please check one ICD-10 Code: Pulmonary arterial hypertension 127.0 127.21 Inoperable Persistent/Recurrent	Therapy Status:

Prescriber will comply with all Surescript's⁺ terms and conditions including confidentiality, commercial messaging, privacy and security, applicable laws, and use of data. All Surescripts disclaimers apply. A full list of terms and conditions is available at <u>https://ubc.com/surescriptsterms/</u>

SECTION 🚯 Prescription

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.							
1 mg Adempas Sample Dispensed Already** / Date: 0.5 mg Adempas Sample Dispensed Already** / Date:							
**Adempas Sample should only be dispensed as a 30-day supply							
Starting dose*:	Titration schedule:						
Adempas 1 mg tablet by mouth three times a day Adempas 0.5 mg tablet by	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 pis to provide the Adempas strength to accommodate titration needs of therapy.						
mouth three times a day	Adempas Tablets: 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg						
Quantity: 30 day supply Refills: Deliver to:	Directions: If systolic blood pressure is >95 mmHg and there are no signs/symptoms of hypotension, up titrate by 0.5 mg 3 time 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 lif at any time, the patient has symptoms of hypotension, decrease the dosage by 0.5 mg 3 times daily. The establist individual dose should be maintained.						
Patient Home	Other special instructions:						
Prescriber Office	Titration Quantity: 30 day supply 14 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 authorizes UBC to use the Surescripts Network [†] on Prescriber's behalf in connection with this prescription.							
PRESCRIBER Dispense as Write	en*:	Date*:					
SIGNATURE REQUIRED Substitutions Per	mitted*:	Date*:					
Return this form and the Adempas REMS Patient Enrollment and Consent Form, along with patient insurance information to the Adempas Program via fax to 1-855-662-5200 or send electronically by visiting www.adempasREMS.com							

Surescripts is a consortium owned by some of the country's largest PBMs that offers information and technology services that supports the electronic transmission of prescriptions between HCPs and other health care organizations.

To report any adverse events, product technical complaints, medication errors or pregnancies associated with the use of Adempas, contact: Bayer at 1-888-842-2937, or send the information to <u>DrugSafety.GPV.US@bayer.com</u>.



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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 (\geq 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 <u>click here</u> to see the full Prescribing Information, including Boxed Warning.

To report any adverse events, product technical complaints, medication errors or pregnancies associated with the use of Adempas, contact: Bayer at 1-888-842-2937, or send the information to DrugSafety.GPV.US@bayer.com.



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

Complete this form which is available at <u>www.adempas-us.com</u>. Prescribers and all female patients must be enrolled in the Adempas REMS Program prior to initiating treatment. Please visit <u>www.AdempasREMS.com</u> to access the Adempas REMS materials including the *Adempas REMS Patient Enrollment and Consent Form*, and fax them along with patient insurance information to the Adempas Program at 1-855-662-5200 or send electronically by visiting <u>www.adempasREMS.com</u>.

SECTION 🕘 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, (B) insurance benefit verification for Adempas and financial assistance for eligible patients and (C) 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. 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 by contacting myAIM via telephone at 1-855-423-3672 or until your HIPAA Authorization expires.

C: Digital Educational Information – e-mail address:

Please enroll me in: (check all that apply) A: Nursing

B: Benefits Verification and Financial Assistance

0

Patient - please initial here to confirm your optional elections: _

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

THIS AREA INTENTIONALLY LEFT BLANK

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PATIENT HIPAA AUTHORIZATION

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 and 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 help with my insurance coverage questions for Bayer medications
- To determine if I qualify for other Bayer patient support programs
- To determine my eligibility for other sources of prescription medication financial assistance
- 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, sales support purposes, and as necessary to comply with applicable laws
- Bayer may contact me for potential adverse event follow-up information

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.
- I may opt-out of being contacted for market research feedback, sales support purposes, and still enroll in the patient support program.
- 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 (i) medical treatment or medication or (ii) coverage, payment, enrollment in or eligibility in benefits from my health plan. 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, pharmacies 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	Patient Name (print):		
	Patient (or legal guardian) Signature*:	Date (mm/dd/yyyy):	
If signed by a leg	gal representative —		
	Print Name:	Relationship to patient:	

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