# The Adempas Enrollment Journey

## A guide to Adempas access information

### INDICATIONS

- Adempas (riociguat) tablets 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.**

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

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

# Enrollment process



## All Sections

All sections filled out in blue in the sample form shown on the right must be completed before submitting.

## Section 2

**Initiation Setting**
Check the box if the patient is starting Adempas in a hospital setting.

**Insurance Information**
Does your patient have prescription insurance?
*Medical and prescriptions may be two separate cards.*

**Diagnosis**
Select the most appropriate ICD-10-CM for the patient

- For PAH: choose newly or previously diagnosed
- For CTEPH: choose inoperable or persistent/recurrent

**ICD-10-CM codes* are relevant to coding for CTEPH and PAH diagnosis**
Coding and classifying the patient's diagnosis and condition are important to support the medical necessity for patients taking Adempas

| PAH (WHO Group 1) | |
|---|---|
| **ICD-10-CM Code** | **Code Description** |
| I27.0 | Primary pulmonary arterial hypertension |
| I27.21 | Secondary arterial pulmonary hypertension |
| **CTEPH (WHO Group 4)** | |
| **ICD-10-CM Code** | **Code Description** |
| I27.24 | Chronic thromboembolic pulmonary hypertension |

*This list is for coding purposes only and not a complete list of ICD-10-CM codes. This list does not suggest approval uses or indications.

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

**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*, and fax them along with patient insurance information to the Adempas Program at 1-855-662-5200 or send electronically by visiting www.adempasREMS.com.**

### SECTION 1 Contact Information

**Patient Contact Information (* indicates required field)**

| | | | | |
|---|---|---|---|---|
| Patient First Name*: Jane | Patient Last Name*: Smith | | Birthdate* (MM/DD/YYYY): 12/01/1972 | Gender*: ☐ Male ☑ Female |
| Address*: 1 Bayer Drive | City*: Whippany | State*: NJ | Zip Code*: 07981 | Preferred Phone*: 555-555-5555 |
| Email: jane.smith@email.com | Preferred Language: ☐ English ☐ Spanish ☐ Other (specify) | | | OK to leave detailed message? ☐ Yes ☐ No |
| Alternate Contact Name: | Alternate Contact Phone: | | Relationship to Patient: | |

**Prescriber Contact Information (* indicates required field)**

| | | | | |
|---|---|---|---|---|
| Prescriber First Name*: Robert | Prescriber Last Name*: Jones | | | NPI*: 10000000000000 |
| Address Line 1*: 1800 Orleans Street | Address Line 2: | City: Baltimore | State: MD | Zip Code: |
| Office Contact: Jennifer Anderson | Phone: 222-333-4444 | Fax: 333-444-5555 | 21287 | |

### 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 DRUG BENEFITS (FRONT AND BACK OF CARD) WITH THIS FORM.**

**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

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 https://ubc.com/surescriptsterms/

### SECTION 3 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*:**
☑ **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: 5

Deliver to:
☑ Patient Home
☐ Prescriber Office

**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: 11

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 SIGNATURE REQUIRED | | |
|---|---|---|
| | **Dispense as Written*:** | **Date*:** |
| | **Substitutions Permitted*:** | **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 DrugSafety.GPV.US@bayer.com.

**PP-ADE-US-2438-1**
**October 2021**

**Phone: 1-855-4ADEMPAS (1-855-423-3672) Fax: 1-855-662-5200**
**www.adempasREMS.com**

Robert Jones 1/5/2020

## Section 3

**Prescription Starting Dose and Titration Schedule**

- **Starting dose** can be selected with # of refills
- **Titration schedule** can be selected with # of refills

*In addition to the Adempas Prescription and Enrollment Form, some states may require a second prescription to be sent directly to the specialty pharmacy (Accredo or Caremark).*

**Prescription Healthcare Nurse Interactions**

- In partnership with your patient, you will discuss if your patient will decide to choose to have follow-up healthcare nurse interactions, which is part of the patient support program. Physicians cannot request nursing services
- As a result, the prescriber will select one of two options in this section
- **NOTE:** If the option for healthcare nurse interactions is selected in Section 3, it **must also be selected in Section 4. See below**

**Prescribers are required to sign and date this section.**

**3 simple ways to enroll**

1. Electronically with e-signature at AdempasHCP.com
2. Email: AdempasSupport@ubc.com
3. Fax: 1-855-662-5200

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

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# Enrollment process (continued)

To prescribe Adempas, the following forms must be completed and submitted with signatures:

- Adempas Prescription and Patient Support Program Enrollment Form
  ***Only the prescription portion of this form is required to be completed in order to initiate and fulfill a prescription. The Patient Support Enrollment section is optional and allows patients to register for some or all of the patient support program***
  – **THE PHYSICIAN CANNOT ORDER PATIENT SUPPORT SERVICES**
- Adempas REMS Patient Enrollment and Consent Form
  ***Female patients only***

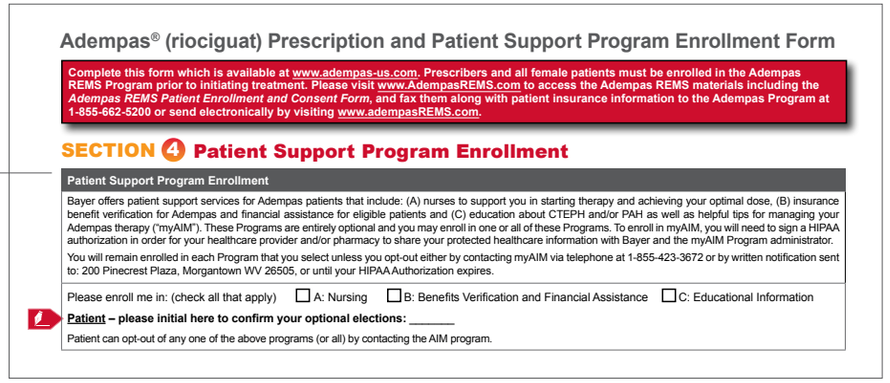
**Be sure to include a copy of the patient's insurance card. Both the front and back of the card are required with the completed enrollment forms.**

## Adempas Prescription and Patient Support Program Enrollment Form *THE PATIENT SUPPORT ENROLLMENT SECTION IS FOR PATIENTS ONLY*

### Section 4 – FOR PATIENTS ONLY

**Optional Patient Support Program Enrollment for patients**

- Inform patients of the option to enroll in the Aim Patient Support Program, which includes: follow-up nurse interactions, financial assistance, and educational information
- If the patient chooses to enroll in the support program, the patient must check the boxes for the services they choose to register for and initial to confirm their elections
- **If patients elect educational information, patients must write their initials. This program is optional for patients.**



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

**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*, and fax them along with patient insurance information to the Adempas Program at 1-855-662-5200 or send electronically by visiting www.adempasREMS.com.**

**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, (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 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.

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

**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.

### HIPAA Authorization

**Written Permission to Share Protected Health Information**
All patients (male or female) must sign and date if they choose to receive any Bayer services or communications.

***Patients may choose to elect. This is optional for patients.***

**PATIENT TO SIGN AND DATE**

**Patient Name (print):** _____

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

***If signed by a legal representative —***
**Print Name:** _____ **Relationship to patient:** _____

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

Adempas® riociguat tablets
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# Adempas REMS Program enrollment

## For female patients only

For all female patients, Adempas is only available through a restricted program under the Adempas Risk Evaluation and Mitigation Strategy (REMS) Program. All female patients must be enrolled in the Adempas REMS program, and the Adempas REMS Patient Enrollment Form must be completed in addition to the Prescription and Patient Support Program Enrollment Form. For REMS enrollment, patient and prescriber signatures will be required on both forms.

## Adempas REMS Patient Enrollment and Consent Form

### All Sections

All sections filled out in blue in the sample form shown on the right must be completed before submitting.

### Section 2

**Statement of Medical Necessity**
Please check a box for diagnosis of PAH or CTEPH:

- If CTEPH, specify "Chronic thromboembolic pulmonary hypertension (inoperable)"

—OR—

- "Chronic thromboembolic pulmonary hypertension (after surgical treatment)"
- Check PH status for "Newly diagnosed" or "Previously diagnosed"

### Section 5

**Prescriber Authorization**
Complete the prescriber authorization section–within this section, only one box should be checked:

- Indicate if pregnancy test has been completed for females of reproductive potential (FRP)

—OR—

- Indicate if not FRP, meaning no pregnancy test required. Must sign and date the form

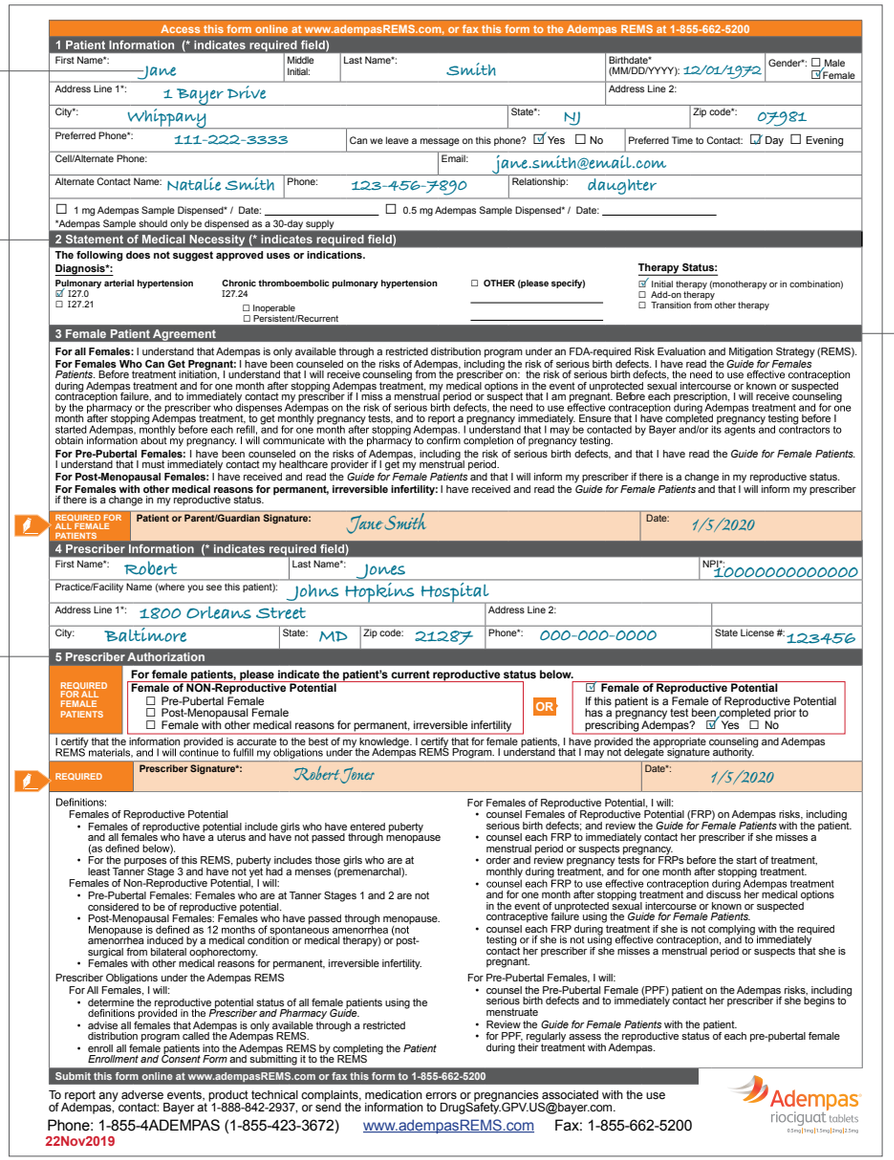
**In Section 5: Prescriber must sign and date for completion.**

**Females of Reproductive Potential who are able to get pregnant are females who:**

- Have entered puberty, even if they have not started their period, have a uterus, and have not gone through menopause
- Examples of females considered reproductive who may be on birth control (contraception): Tubal ligation, oral/pills, rings, patches, and IUDs

**Females of Non-Reproductive Potential who are NOT able to get pregnant are females who:**

- Have not yet entered puberty, do not have a uterus (hysterectomy), or have gone through menopause (have not had a period for at least 12 months for natural reasons, or who have had their ovaries removed)



Access this form online at www.adempasREMS.com, or fax this form to the Adempas REMS at 1-855-662-5200

**1 Patient Information (* indicates required field)**

First Name*: Jane | Middle Initial: | Last Name*: Smith | Birthdate* (MM/DD/YYYY): 12/01/1972 | Gender*: ☐ Male ☑ Female

Address Line 1*: 1 Bayer Drive | Address Line 2:

City*: Whippany | State*: NJ | Zip code*: 07981

Preferred Phone*: 111-222-3333 | Can we leave a message on this phone? ☑ Yes ☐ No | Preferred Time to Contact: ☑ Day ☐ Evening

Cell/Alternate Phone: | Email: jane.smith@email.com

Alternate Contact Name: Natalie Smith | Phone: 123-456-7890 | Relationship: daughter

☐ 1 mg Adempas Sample Dispensed* / Date: _____ ☐ 0.5 mg Adempas Sample Dispensed* / Date: _____

*Adempas Sample should only be dispensed as a 30-day supply

**2 Statement of Medical Necessity (* indicates required field)**

**The following does not suggest approved uses or indications.**

**Diagnosis*:**

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

**3 Female Patient Agreement**

**For all Females:** I understand that Adempas is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).
**For Females Who Can Get Pregnant:** I have been counseled on the risks of Adempas, including the risk of serious birth defects. I have read the *Guide for Females Patients*. Before treatment initiation, I understand that I will receive counseling from the prescriber on: the risk of serious birth defects, the need to use effective contraception during Adempas treatment and for one month after stopping Adempas treatment, my medical options in the event of unprotected sexual intercourse or known or suspected contraception failure, and to immediately contact my prescriber if I miss a menstrual period or suspect that I am pregnant. Before each prescription, I will receive counseling by the pharmacy or the prescriber who dispenses Adempas on the risk of serious birth defects, the need to use effective contraception during Adempas treatment and for one month after stopping Adempas treatment, to get monthly pregnancy tests, and to report a pregnancy immediately. Ensure that I have completed pregnancy testing before I started Adempas, monthly before each refill, and for one month after stopping Adempas. I understand that I may be contacted by Bayer and/or its agents and contractors to obtain information about my pregnancy. I will communicate with the pharmacy to confirm completion of pregnancy testing.
**For Pre-Pubertal Females:** I have been counseled on the risks of Adempas, including the risk of serious birth defects, and that I have read the *Guide for Female Patients*. I understand that I must immediately contact my healthcare provider if I get my menstrual period.
**For Post-Menopausal Females:** I have received and read the *Guide for Female Patients* and that I will inform my prescriber if there is a change in my reproductive status.
**For Females with other medical reasons for permanent, irreversible infertility:** I have received and read the *Guide for Female Patients* and that I will inform my prescriber if there is a change in my reproductive status.

REQUIRED FOR ALL FEMALE PATIENTS | **Patient or Parent/Guardian Signature:** Jane Smith | Date: 1/5/2020

**4 Prescriber Information (* indicates required field)**

First Name*: Robert | Last Name*: Jones | NPI*: 1000000000000

Practice/Facility Name (where you see this patient): Johns Hopkins Hospital

Address Line 1*: 1800 Orleans Street | Address Line 2:

City: Baltimore | State: MD | Zip code: 21287 | Phone*: 000-000-0000 | State License #: 123456

**5 Prescriber Authorization**

REQUIRED FOR ALL FEMALE PATIENTS

**For female patients, please indicate the patient's current reproductive status below.**

**Female of NON-Reproductive Potential**
☐ Pre-Pubertal Female
☐ Post-Menopausal Female
☐ Female with other medical reasons for permanent, irreversible infertility

OR

☑ **Female of Reproductive Potential**
If this patient is a Female of Reproductive Potential has a pregnancy test been completed prior to prescribing Adempas? ☑ Yes ☐ No

I certify that the information provided is accurate to the best of my knowledge. I certify that for female patients, I have provided the appropriate counseling and Adempas REMS materials, and I will continue to fulfill my obligations under the Adempas REMS Program. I understand that I may not delegate signature authority.

REQUIRED | **Prescriber Signature*:** Robert Jones | Date*: 1/5/2020

Definitions:
Females of Reproductive Potential
- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below).
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).

Females of Non-Reproductive Potential, I will:
- Pre-Pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.
- Post-Menopausal Females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.
- Females with other medical reasons for permanent, irreversible infertility.

Prescriber Obligations under the Adempas REMS
For All Females, I will:
- determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber and Pharmacy Guide*.
- advise all females that Adempas is only available through a restricted distribution program called the Adempas REMS.
- enroll all female patients into the Adempas REMS by completing the *Patient Enrollment and Consent Form* and submitting it to the REMS

For Females of Reproductive Potential, I will:
- counsel Females of Reproductive Potential (FRP) on Adempas risks, including serious birth defects; and review the *Guide for Female Patients* with the patient.
- counsel each FRP to immediately contact her prescriber if she misses a menstrual period or suspects pregnancy.
- order and review pregnancy tests for FRPs before the start of treatment, monthly during treatment, and for one month after stopping treatment.
- counsel each FRP to use effective contraception during Adempas treatment and for one month after stopping treatment and discuss her medical options in the event of unprotected sexual intercourse or known or suspected contraceptive failure using the *Guide for Female Patients*.
- counsel each FRP during treatment if she is not complying with the required testing or if she is not using effective contraception, and to immediately contact her prescriber if she misses a menstrual period or suspects that she is pregnant.

For Pre-Pubertal Females, I will:
- counsel the Pre-Pubertal Female (PPF) patient on the Adempas risks, including serious birth defects and to immediately contact her prescriber if she begins to menstruate
- Review the *Guide for Female Patients* with the patient.
- for PPF, regularly assess the reproductive status of each pre-pubertal female during their treatment with Adempas.

**Submit this form online at www.adempasREMS.com or fax this form to 1-855-662-5200**

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.

Phone: 1-855-4ADEMPAS (1-855-423-3672) www.adempasREMS.com Fax: 1-855-662-5200

22Nov2019

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### Section 3

**Female Patient Agreement**

- An enrollment form cannot be processed without female patient signature and date

**Prescribers are required to sign and date this section.**

**When completed, submit all forms online, by email, or fax.**

**3 simple ways to enroll**

1. Electronically with e-signature at AdempasHCP.com
2. Email: AdempasSupport@ubc.com
3. Fax: 1-855-662-5200

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

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# Prior authorization (PA) and appeals process



## Common prior authorization criteria

**Does your patient meet the prior authorization criteria?**

- Consider the commonly required clinical criteria for PAH and CTEPH
- Utilizing a right heart catheterization (RHC), the following hemodynamic parameters can be obtained:

### For both CTEPH and PAH

- Mean pulmonary arterial pressure (mPAP)
- Pretreatment pulmonary capillary wedge pressure (PAWP or PCWP)
- Pulmonary vascular resistance (PVR)

### For CTEPH (WHO Group 4)

- CTEPH was confirmed by RHC
- Include documentation of ventilation/perfusion (V/Q) scan
- Medical reason(s) why a test could not be performed, if applicable

### For PAH (WHO Group 1)

- PAH was confirmed by RHC
- Medical reason(s) why a test could not be performed, if applicable

**The following are items frequently required on a PA for Adempas:**

- Documented diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) or chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4), which may include pertinent patient medical history
- Diagnostic testing and relevant documentation often required:
  - RHC, including documented administration of vasoreactivity test
  - V/Q scan (for CTEPH patients)
  - Medical reason(s) why a test could not be performed, if applicable
  - Include Functional Class
  - Indicate previous treatments that have been tried and provide an explanation when applicable
- Please request approval for the initial dose and each strength for the titration schedule
- For quicker review, indicate on the form or check the box for expedited/urgent review
- It may be possible to request a multi-year authorization or a "lifetime" authorization

**Key points to consider:**

- Provide information from the indication section of the Adempas Prescribing Information for patients studied in clinical trials
- Please consult the payer policy for Adempas coverage to ensure the requirements have been addressed

**If your PA or appeal is denied, please contact your Adempas Access and Coverage Manager (ACM) for additional support**

**For additional support with prior authorization and appeals, contact Aim Support 1-855-4ADEMPAS (1-855-423-3672)**

## 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).

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

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# Prior authorization (PA) and appeals process cont.

## Addressing reasons for denial of prior authorization

- Refer to the denial letter for the specific reasons and directly address the payer* using the guidance below; there may be more than one issue requiring response, and thorough appeals are generally more successful
- Contact the payer for more information if a clear reason for refusal has not been provided

  **Example:** If the denial states "does not meet medical criteria," request the reason, and ask for the specific criteria and data required. It may be possible to obtain that information in writing from the payer.

**There are two options for handling the prior authorization appeals process with a payer:**

### 1. Submit a written appeal letter

- An expedited written review is often also available. A result is generally provided within 24–72 hours, depending on the payer
- However, some payers may consider "expedited" to be 2 weeks or more

### 2. Request a verbal discussion

- Ask to speak directly to a clinical reviewer
- The prescribing physician can also request a peer-to-peer discussion with a cardiologist or pulmonologist to review the appeal
- Verbal discussions may provide the most rapid review of the case and allow the opportunity for back-and-forth discussion

**If the PA or appeal is denied, you can contact your Adempas Access and Coverage Manager (ACM) for additional support**

*Payer refers to any of the following: commercial health plan, Medicare, Medicaid, or any entity paying for prescription drugs.

## Access and Coverage Managers

*An information resource for staff*

**Access and Coverage Manager (ACM)**
*Your resource to help navigate the enrollment and approval process for your Adempas patients*

The ACM can:

- Provide patient and REMS enrollment support
- **Engage with you, your office,** the Aim Support Center, and your Adempas Sales Consultants
- Provide assistance with access and coverage issue resolution
- Offer expertise within managed care policies on the local, state, and national levels



**WARNINGS AND PRECAUTIONS (continued)**

**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.

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

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# Adempas Sampling Program and Hospital Program

## Adempas Sampling Program

**The Adempas Sampling Program will:**

- Allow you to provide the starting dose of Adempas (either 0.5 mg or 1.0 mg) to new patients at no cost
- Provide samples in a convenient 90 count (30-day supply) to ensure your patients have enough product available to titrate*

**Patients enrolled in the Adempas Sampling Program also have the option to receive support from the Aim Patient Support Program, including:**

- Evaluation of insurance coverage and help in securing financial assistance
- Nursing support and patient education materials
- A patient education and counseling call with a pharmacist

**Required forms**

Patient Enrollment and Adempas REMS Program Enrollment are required to participate in the Adempas Sampling Program:

- Adempas Prescription and Patient Support Program Enrollment Form (all patients)
- Adempas REMS Patient Enrollment and Consent Form (female patients only)

Fax all completed forms to the Aim Coordination Center: **1-855-662-5200**

**Contact your representative to receive samples**

*During this time, the Aim Support Program will assist in determining drug coverage for future prescriptions. In the event that more time is required for coverage determination, Bayer will provide product supply for up to 60 days.

## Adempas Hospital Program

**The Adempas Hospital Program can allow you to initiate Adempas in the hospital and continue treatment without interruption upon discharge.**

- Check with your hospital pharmacy to ensure they are REMS certified and can dispense Adempas
- Prescriber completes and submits enrollment forms to include confirmation of starting dose and date and potential discharge date. Also, check the "Yes" box for "Is patient starting in hospital setting?"
- Prescriber completes the Adempas Hospital Program Checklist and faxes to the Aim Support Center with the patient enrollment forms
- Aim processes the enrollment and triages as a priority to the specialty pharmacy
- Adempas is shipped to the patient's home or prescriber's office within 72 hours of completed enrollment or upon hospital discharge
- Complimentary supply (up to 90 days) provided while working through approval process regardless of insurance coverage or lack of coverage

### National Drug Code (NDC)

**For a 3-day supply of Adempas (bottle of 9 tablets):**

- 0.5 mg NDC 50419-250-91
- 1 mg NDC 50419-251-91
- 1.5 mg NDC 50419-252-91
- 2 mg NDC 50419-253-91
- 2.5 mg NDC 50419-254-91

### Ordering through CuraScript

*For hospital distribution only, Adempas is distributed exclusively through CuraScript Specialty Distribution*

Phone: **1-877-599-7748**

Fax: **1-800-862-6208**

## WARNINGS AND PRECAUTIONS (continued)

**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.**

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

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

# Adempas Aim Patient Support Program

## Aim Patient Support helps patients get access to Adempas

- Ensures completed enrollment forms
- Confirms prescriber is REMS certified
- Provides benefits verification
- Sends Prior Authorization (PA) form to prescriber's office
- Refers patients for assistance programs as needed
- Triages enrollment to specialty pharmacy

**Access and Financial Support**

**Aim Nursing Support**


**myAim Education & Encouragement**

### 2 easy ways for your patients to enroll in the Aim Patient Support Program

**PHYSICIANS CANNOT ORDER PATIENT SUPPORT SERVICES**

**Patients can complete the Patient Support section of the Prescription Enrollment Form**

**Patients can call the Aim Support Center at 1-855-4ADEMPAS (1-855-423-3672)**

## Aim Access and Financial Support

### Private Insurance/Commercial

**Co-pay Assistance Program***


- The Co-pay Assistance Program is for all patients insured through commercial payers; regardless of income, patients will pay $0 for Adempas

**Quick Start Program (QSP)†**

**Who is eligible?**

- Only available to patients with commercial plans with no step edits

**How does the QSP work?**

- Once benefit investigation is completed, referral is triaged to the respective specialty pharmacy for dispensing

**When are benefits processed? When will therapy be available?**

- Benefits are not processed until coverage is secured
- No-cost supply (up to 90 days) will be dispensed

**What happens when coverage is secured?**

- Once coverage is secured, referral moves to commercial coverage without disruption of therapy

**How do patients get started in the QSP?**

- Patients are automatically enrolled if they have commercial insurance plans

### Government and Uninsured/Underinsured

- **Patient Assistance Program‡:** Patients who are unable to afford their medication may be eligible to receive Adempas at no cost for one year from the date of acceptance
- **Independent Foundation Assistance:** Patients requiring additional financial assistance for out-of-pocket costs will be referred to independent charitable organizations

### All Patients

- **Adempas Hospital Program§:** Patients who initiate treatment in the hospital can continue Adempas at no cost without interruption upon discharge while awaiting insurance confirmation. Patients may receive treatment up to 90 days while awaiting insurance approval. See page 6 for full details
- **Interim Assistance:** Patients receive Adempas at no cost when immediate insurance coverage cannot be secured or there are gaps in coverage

*Patients must have private commercial insurance with a percentage coinsurance or co-pay requirement. Medicare or Medicaid patients are ineligible for the $0 co-pay program. Assistance is for one year, after which patients must re-apply. Patients must notify the program of any change in their insurance status. Patients in certain states may be ineligible.

†For plans with no step edits.

‡Medicare Part D patients will be enrolled based on calendar year.

§Some restrictions may apply.

## WARNINGS AND PRECAUTIONS (continued)

**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.

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

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

# Nursing support and patient education

## Aim Nursing Support

**You can expect:**

- Adempas information for patients and caregivers
- Explanation of titration
- Review of your patient's status for titration of doses
- Follow-up with the prescriber
- Explanation and review of your patient's schedule of nurse contacts (if requested by the patient)
- 24/7 hotline for your patients

Accredo and Caremark are the pharmacies that make up the Adempas Aim Nursing Support.

**PHYSICIANS CANNOT REQUEST NURSING SERVICES FOR PATIENTS**

## myAim Education & Encouragement

**Information for your patient's treatment journey**

- Educational support through key stages of treatment and what to expect along the way
- Personalized communications for patients and caregivers throughout treatment
- Tips for patients on what to talk with their doctors about
- Information about other online resources and support

**Patients must complete and sign the Patient Support section of the Adempas Prescription and Patient Support Program Enrollment Form to opt in to myAim Education & Encouragement**

## 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 for full Prescribing Information, including Boxed Warning.**



Bayer
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PP-ADE-US-2374-1 October 2021

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