



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

**RIOCIGUAT**

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIOCIGUAT	ADEMPAS	40644		GPI-10 (4013405000)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
- The patient is NOT concurrently taking nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

If yes, continue to #2.

If no, continue to #3.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?

- Mean pulmonary artery pressure (PAP) greater than 20 mmHg
- Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
- Pulmonary vascular resistance (PVR) greater than 2 Wood units

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
- The patient has persistent or recurrent disease after surgical treatment OR the patient is not a candidate for surgery or has inoperable CTEPH
- The patient has NYHA-WHO Functional Class II to IV symptoms
- The patient is NOT concurrently taking nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

RIOCIQUAT

INITIAL CRITERIA (CONTINUED)

**INITIAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **RIOCIQUAT (Adempas)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) World Health Organization (WHO: Group 4: a way to classify the severity of disease)
  2. Pulmonary arterial hypertension (PAH: type of high blood pressure that affects the arteries in the lungs and in the heart) World Health Organization (WHO Group 1: a way to classify the severity of disease)
- B. **If you have pulmonary arterial hypertension, approval also requires:**
1. You are 18 years of age or older
  2. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)
  3. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on all of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    - a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    - b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    - c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
  4. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)
- C. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
1. You are 18 years of age or older
  2. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)
  3. You have persistent or recurrent disease after surgical treatment (it continues to exist or returns after surgery) OR you are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
  4. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
  5. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

***(Initial denial text continued on next page)***

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STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

RIOCIQUAT

**GUIDELINES FOR USE (CONTINUED)**

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**RENEWAL CRITERIA**

1. Does the patient have one of the following diagnoses?
  - Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO (World Health Organization) Group 4)
  - Pulmonary arterial hypertension (PAH) (WHO Group 1)

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** See the renewal denial text at the end of the guideline.

2. Is the patient concurrently taking nitrate or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)?

If yes, do not approve.

**DENIAL TEXT:** See the renewal denial text at the end of the guideline.

If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
  - The patient has shown improvement from baseline in the 6-minute walk distance test
  - The patient remains stable from baseline in the 6-minute walk distance test with a stable or improved World Health Organization (WHO) functional class

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**

If no, do not approve.

**DENIAL TEXT:** See the renewal denial text at the end of the guideline.

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RIOCIQUAT

RENEWAL CRITERIA (CONTINUED)

**RENEWAL DENIAL TEXT:** \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIOCIQUAT (Adempas)** requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
  1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) World Health Organization (WHO Group 4: a way to classify the severity of disease)
  2. Pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group 1: a way to classify the severity of disease)
- B. You are not concurrently (at the same time) taking nitrate or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)
- C. You show improvement from baseline in the 6-minute walk distance test OR remain stable from baseline in the 6-minute walk distance test with a stable or improved World Health Organization functional class (WHO-FC: classification system for heart failure)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adempas.

**REFERENCES**

- Adempas [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.

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