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. Is the requested medication prescribed by or given in consultation with a cardiologist or pulmonologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meets **ALL** of the following criteria?
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) > 3 Wood units
   - NYHA-WHO Functional Class II-IV symptoms
   - The patient had a previous trial or contraindication to phosphodiesterace-5 inhibitors (e.g. Revatio or Adcirca)
   - The patient is not concurrently taking nitrate or nitric oxide donors (e.g. amyl nitrate), phosphodiesterase inhibitors (e.g. sildenafil, tadalafil, or 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 #90 per 30 days.**
   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of a persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) WHO Group 4 and meet **ALL** of the following criteria?
   - 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. sildenafil, tadalafil, or 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 #90 per 30 days.**
   If no, do not approve.
   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 **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of a persistent/recurrent chronic thromboembolic pulmonary hypertension World Health Organization Group 4 (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) or a diagnosis of pulmonary arterial hypertension World Health Organization Group 1 (PAH: type of high blood pressure affecting lungs and arteries)
   B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)
   C. **If you have pulmonary arterial hypertension, approval also requires:**
      1. You have a documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
         a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
         b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
         c. Pulmonary vascular resistance (PVR) greater than 3 Wood units
      2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
      3. You had a previous trial of a phosphodiesterase-5 inhibitor such as Revatio or Adcirca, unless there is a medical reason why you cannot (contraindication)
      4. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

D. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
   1. 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
   2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   3. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

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) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
   - 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. Has the patient shown improvement from baseline in the 6-minute walk distance?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance?

   If yes continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

4. Has the patient World Health Organization (WHO) functional class remained stable or has improved?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, do not approve.
   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 **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:
   A. You have one of the following diagnoses:
      i. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO (World Health Organization) Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
      ii. Pulmonary arterial hypertension (PAH) (WHO Group 1)
   B. You show improvement from baseline in the 6-minute walk distance **OR** have a stable 6-minute walk distance with a stable or improved World Health Organization (WHO) functional class.

   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.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
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