



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/19/2021  
LAST REVIEW DATE:  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

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## REZUROCK™ (belumosudil) oral

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**



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### Criteria:

- **Criteria for initial therapy:** Rezero (belumosudil) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Transplant Specialist
  2. Individual is 12 years of age (who weigh at least 40 kg) or older
  3. A confirmed diagnosis of **ONE** of the following:
    - a. Chronic graft-versus-host disease (chronic GVHD) after failure of 2-5 prior lines of systemic therapy
    - b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
  4. Individual received an allogeneic hematopoietic cell transplant
  5. Individual is receiving stable dose of glucocorticoid therapy
  6. There is evidence of persistent chronic GVHD manifestations
  7. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    - a. Negative pregnancy test in a woman of child bearing potential
    - b. **ONE** of the following:
      - i. **For individual 16 years of age or older:** Karnofsky Performance Score of greater than or equal to 60
      - ii. **For individual between 12 years of age and less than 16 years of age:** Lansky Performance Score of greater than or equal to 60
  8. There are no significant interacting drugs

**Initial approval duration:** 6 months

- **Criteria for continuation of coverage (renewal request):** Rezero (belumosudil) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Transplant Specialist
  2. Individual's condition has responded while on therapy
    - a. Response is defined as **TWO** of the following:



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- i. No evidence of disease progression
  - ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
  - iii. Achieved and maintains at least a 7-point reduction in Lee Chronic Graft-versus-Host Symptom Scale Score over baseline
3. Individual has been adherent with the medication
  4. Individual has not developed any significant adverse drug effects that may exclude continued use
    - a. Significant adverse effect such as:
      - i. Hepatotoxicity
      - ii. Other life-threatening adverse effects
  5. There are no significant interacting drugs

**Renewal duration:** 12 months

➤ Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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### **Description:**

Rezurock (belumosudil) is a kinase inhibitor indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

Belumosudil is an inhibitor of rho-associated, coiled-coil containing protein kinase (ROCK) which inhibits ROCK1 and ROCK2. Belumosudil down-regulates proinflammatory responses via regulation of signal transducer and activator transcription (STAT) 3 and STAT 5 phosphorylation and shifting Th17/Treg balance in *ex-vivo* or *in vitro* human T cell assays. Belumosudil also inhibited aberrant pro-fibrotic signaling, *in vitro*. *In vivo*, belumosudil demonstrated activity in animal models of chronic GVHD.

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### **Definitions:**

Clinical manifestations of chronic GVHD include:

- Skin involvement (e.g., resembling lichen planus or cutaneous manifestations of scleroderma)
- Dry oral mucosa with ulcerations and sclerosis



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- Gastrointestinal tract effects (e.g., exudates, erosions, ulceration)
- Lungs (e.g., bronchiolitis obliterans diagnosed by biopsy)

Acute GVHD commonly demonstrate a classic maculopapular rash; abdominal cramps with diarrhea; and arising serum bilirubin concentration

**Karnofsky Performance Scale:**

Score	Description	
100	Normal, no complaints, no evidence of disease	Able to carry on normal activity and to work
90	Able to carry on normal activity, only minor signs or symptoms of disease present	
80	Normal activity with effort, some signs or symptoms of disease present	No special care needed
70	Cares for self, but unable to carry on normal activity or do active work	Unable to work but able to live at home and care for most personal needs
60	Requires occasional assistance from others, but is able to care for most of his/her needs	
50	Requires considerable assistance from others and needs frequent medical care	Various degrees of assistance may be needed
40	Disabled, requires special care and assistance	Unable to care for self Requires equivalent of institutional or hospital care
30	Severely disabled, hospitalization indicated, but death not imminent	
20	Very sick, hospitalization indicated, active support treatment is necessary but death not imminent	
10	Moribund, fatal process progressing rapidly	
0	Dead	

**Lansky Performance Scale:**

Score	Description
100	Fully active, normal
90	Minor restrictions in physical strenuous activity
80	Active, but tires more quickly
70	Both greater restriction of, and less time spent in, play activity
60	Up and around, but minimal active play; keeps busy with quieter activities
50	Gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities
40	Mostly in bed, participates in quiet activities
30	In bed, needs assistance even for quiet play
20	Often sleeping, play entirely limited to very passive activities
10	No play, does not get out of bed
0	Dead

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### Lee Chronic Graft-versus-Host Symptom Scale:

*Please let us know whether you have been bothered by any of the following problems in the past month.*

	Not at all	Slightly	Moderately	Quite a bit	Extremely
<b>SKIN:</b>					
a. Abnormal skin color	0	1	2	3	4
b. Rashes	0	1	2	3	4
c. Thickened skin	0	1	2	3	4
d. Sores on skin	0	1	2	3	4
e. Itchy skin	0	1	2	3	4
<b>EYES AND MOUTH:</b>					
f. Dry eyes	0	1	2	3	4
g. Need to use eyedrops frequently	0	1	2	3	4
h. Difficulty seeing clearly	0	1	2	3	4
i. Need to avoid certain foods due to mouth pain	0	1	2	3	4
j. Ulcers in mouth	0	1	2	3	4
k. Receiving nutrition from an intravenous line or feeding tube	0	1	2	3	4
<b>BREATHING:</b>					
l. Frequent cough	0	1	2	3	4
m. Colored sputum	0	1	2	3	4
n. Shortness of breath with exercise	0	1	2	3	4
o. Shortness of breath at rest	0	1	2	3	4
p. Need to use oxygen	0	1	2	3	4
<b>EATING AND DIGESTION:</b>					
q. Difficulty swallowing solid foods	0	1	2	3	4
r. Difficulty swallowing liquids	0	1	2	3	4
s. Vomiting	0	1	2	3	4
t. Weight loss	0	1	2	3	4
<b>MUSCLES AND JOINTS:</b>					
u. Joint and muscle aches	0	1	2	3	4
v. Limited joint movement	0	1	2	3	4
w. Muscle cramps	0	1	2	3	4
x. Weak muscles	0	1	2	3	4
<b>ENERGY:</b>					
y. Loss of energy	0	1	2	3	4
z. Need to sleep more/take naps	0	1	2	3	4
aa. Fevers	0	1	2	3	4
<b>MENTAL AND EMOTIONAL:</b>					
bb. Depression	0	1	2	3	4
cc. Anxiety	0	1	2	3	4
dd. Difficulty sleeping	0	1	2	3	4

### Resources:

Rezurock (belumosudil) product information, revised by Kadmon Pharmaceuticals, LLC. 07-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on July 30, 2021.

Chao NJ. Clinical manifestations, diagnosis, and grading of chronic graft-versus-host disease. In: UpToDate, Negrin RS, Rosmarin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed on August 08, 2021.

Chao NJ, Zeiser R. Treatment of chronic graft-versus-host disease. In: UpToDate, Negrin RS, Rosmarin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed on August 09, 2021.



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ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT03640481. A Phase 2, Randomized Multicenter Study to Evaluate the Efficacy and Safety of KD025 in Subjects with Chronic Graft Versus Host Disease (cGVHD) After At Least 2 Prior Lines of Therapy (The ROCKstar Study). Last Update Posted Aug 03, 2021. Available from: <http://clinicaltrials.gov>. Accessed August 08, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Hematopoietic Cell Transplantation (HCT): Pre-Transplant Recipient Evaluation and Management of Graft-Versus-Host disease Version 3.2021 – Updated July 26, 2021. Available at <https://www.nccn.org>. Accessed on August 08, 2021.

Lee SJ, Cook EF, Soiffer R, Antin JH.: Development and validation of a scale to measure symptoms of chronic graft-versus-host disease. *Biology of Blood and Marrow Transplantation* 2002; 8:444-452. Accessed August 09, 2021

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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