Rezurock (belumosudil) Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date 05-01-2024

Date of Origin 11-01-2023

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Rezurock® (belumosudil) Tablet	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		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Graft-Versus-Host-Disease	Chronic graft-versus-host disease (cGVHD) is the leading cause of non-relapse mortality (NRM) after an allogeneic hematopoietic cell transplant (HCT), has a profound impact on quality of life. cGVHD usually develops within the first year after HCT in most patients, but it can also develop many years later. cGVHD affects multiple organ systems and is characterized by fibrosis and variable clinical features resembling autoimmune disorders.(2) Standard of care in the treatment of cGvHD depends on the particular organ(s) or site(s) that is/are affected and adopted treatments can be topical or systemic. About 50%–60% of patients with cGvHD will require a second-line treatment within 2 years.(4,5) Approximately 40% to 50% of patients with acute or chronic GVHD develop steroid-refractory disease, which is associated with high mortality. Currently, ruxolitinib, ibrutinib, and belumosudil are the only FDA-approved agents for treatment of steroid-refractory cGVHD.(2,3)
Efficacy	Study KD025-213 (NCT03640481) was a randomized, open-label, multicenter study of Rezurock for treatment of patients with chronic GVHD who had received 2 to 5 prior lines of systemic therapy and required additional treatment. There were 66 patients treated with Rezurock 200 mg taken orally once daily. Concomitant treatment with supportive care therapies for chronic GVHD was permitted. Concomitant treatment with GVHD prophylaxis and standard care systemic chronic GVHD therapies was permitted as long as the subject has been on a stable dose for at least 2 weeks prior to study. Initiation of new systemic chronic GVHD therapy while on study was not permitted.(1,6) The efficacy of Rezurock was based on overall response rate (ORR) through Cycle 7 Day 1 where overall response included complete response or partial response according to the 2014 NIH Response Criteria. The ORR was 75% (95% CI: 63, 85). The median duration of response, calculated from first response to progression, death, or new systemic therapies for chronic GVHD, was 1.9 months (95% CI: 1.2, 2.9). The

	median time to first response was 1.8 months (95% CI: 1.0, 1.9). In patients who achieved response, no death or new systemic therapy initiation occurred in 62% (95% CI: 46, 74) of patients for at least 12 months since response.(1,6) ORR results were supported by exploratory analyses of patient-reported symptom bother which showed at least a 7-point decrease in the Lee Symptom Scale summary score through Cycle 7 Day 1 in 52% (95% CI: 40, 65) of patients. The median duration of response was 54 weeks; 44% of patients remained on therapy for greater than or equal to one year. Overall median follow-up was 14 months.(1,6)
Safety	Rezurock carries no boxed warnings or contraindications.(1)

REFERENCES

Number	Reference
1	Rezurock prescribing information. Kadmon Pharmaceuticals, LLC. April 2023.
2	National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology - Hematopoietic Cell Transplantation (HCT). Version 1.2023.
3	Hamilton BK. Updates in Chronic Graft-Versus-Host Disease. Hematology Am Soc Hematol Educ Program. 2021;1:648–654.
4	Wolff D, Fatobene G, Rocha V, et al. Steroid-Refractory Chronic Graft-Versus-Host Disease: Treatment Options and Patient Managment. Bone Marrow Transplant. 2021 Jul;56:2079-2087.
5	Saidu NEB, Bonini C, Dickinson A, et al. New Approaches for the Treatment of Chronic Graft-Versus-Host Disease: Current and Future Directions. Front Immunol. 2020;11:578314.
6	Cutler C, Lee SJ, Arai S. Belumosudil for Chronic Graft-Versus-Host Disease after Two or More Prior Lines of Therapy: the ROCKstar Study. Blood. 2021 Dec;138(22):2278-2289.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Rezurock	belumosudil mesylate tab	200 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Rezurock	Belumosudil Mesylate Tab	200 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Rezurock	belumosudil mesylate tab	200 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Rezurock	Belumosudil Mesylate Tab	200 MG	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
Rezurock

      1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

   B. BOTH of the following:
      1. The patient has chronic graft-versus-host disease (chronic GVHD) **AND**
      2. ONE of the following:
         A. The patient's medication history includes therapy with at least two prior lines of systemic therapy AND ONE of the following:
            1. The patient has had an inadequate response to at least two prior lines of systemic therapy **OR**
            2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over at least two prior lines of systemic therapy **OR**
         B. The patient has an intolerance or hypersensitivity to therapy with at least two prior lines of systemic therapy **OR**
         C. The patient has an FDA labeled contraindication to ALL lines of systemic therapy **OR**
         D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
         E. The prescriber has provided documentation that systemic therapy cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
2. If the patient has an FDA approved indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, oncologist) or has consulted with a specialist in the area of the patient's diagnosis **AND**

Module	Clinical Criteria for Approval
	4. The patient does NOT have any FDA labeled contraindications to therapy with the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization Review process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, oncologist) or has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the for the requested indication **Length of Approval:** 12 months