CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Rezurock (belumosudil)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Rezurock, approved by the FDA in 2021, is a small molecule kinase inhibitor indicated for patients 12 years of age and older with chronic graft-versus-host disease (cGVHD) after failure of at least 2 prior lines of systemic therapy. GVHD, a common complication following allogeneic hematopoietic stem cell transplant (HSCT), occurs in about 50% of HSCT patients. Prednisone is the mainstay of initial therapy but at least half of patients require at least 2 lines of therapy.
Rezurock is the first rho-associated, coiled-coil kinase 2 (ROCK2) inhibitor. The ROCK2 pathway modulates inflammatory response and fibrotic processes. ROCK2 inhibition is thought to both restore immune homeostasis and reduce fibrotic processes, which makes Rezurock unique from other pharmacologic treatment options. Approval was based on the phase 2 ROCKstar study.

Rezurock (belumosudil) will be considered for coverage when the following criteria are met:

Chronic Graft-Versus-Host Disease (cGVHD)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a transplant or hematology/oncology specialist; AND
3. Member has a diagnosis of cGVHD following allogeneic hematopoietic cell transplant; AND
4. Member has failed at least 2 prior lines of systemic therapy, i.e., systemic corticosteroid and another systemic treatment (calcineurin inhibitor, Jakafi, mycophenolate mofetil, sirolimus, methotrexate, Imbruvica); AND
5. If the member is on a chronic proton pump inhibitor (e.g., omeprazole), the member must attempt to discontinue it or switch to an alternate agent such as an H2 blocker (e.g., famotidine).
6. **Dosage allowed/Quantity limit:** 200 mg orally once daily. (QL: 30 tablets per 30 days).
   NOTE: Patients who must remain on a proton pump inhibitor will require 200 mg twice daily (and a QL override).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement of signs and symptoms of disease in at least 1 organ/site, without progression in any other organ/site.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Rezurock (belumosudil) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/29/2021	New policy created for Rezurock.
03/07/2024	Updated references. Removed “persistent manifestations” and added “following allogeneic hematopoietic cell transplant.”

References:

1. Rezurock [prescribing information]. Kadmon Pharmaceuticals, LLC; 2023.
2. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT). Version 3.2023. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed March 8, 2024.
3. Jagasia M, Lazaryan A, Bachier CR, et al. ROCK2 Inhibition With Belumosudil (KD025) for the Treatment of Chronic Graft-Versus-Host Disease. *J Clin Oncol*. 2021;39(17):1888-1898. doi:10.1200/JCO.20.02754
4. Wolff D, Fatobene G, Rocha V, Kröger N, Flowers ME. Steroid-refractory chronic graft-versus-host disease: treatment options and patient management. *Bone Marrow Transplant*. 2021;56(9):2079-2087. doi:10.1038/s41409-021-01389-5
5. Penack O, Marchetti M, Aljurf M, et al. Prophylaxis and management of graft-versus-host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. *Lancet Haematol*. 2024;11(2):e147-e159. doi:10.1016/S2352-3026(23)00342-3
6. Cutler C, Lee SJ, Arai S, et al. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study [published correction appears in Blood. 2022 Mar 17;139(11):1772]. *Blood*. 2021;138(22):2278-2289. doi:10.1182/blood.2021012021

Effective date: 10/01/2024
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