

Drug Policy

Policy:	Rezurock (belumosudil)	Annual Review Date: 09/21/2023
		Last Revised Date: 09/21/2023

OVERVIEW

Rezurock, a kinase inhibitor, is indicated for the treatment of patients ≥ 12 years of age with **chronic graft-versus-host disease** (GVHD) after failure of at least two prior lines of systemic therapy.

POLICY STATEMENT

This policy involves the use of Rezurock. Prior authorization is recommended for pharmacy benefit coverage of Rezurock. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rezurock is recommended in those who meet the following criteria:

1. Graft-Versus-Host Disease

Criteria. Patient must meet the following criteria (A, B, and C):

- A) Patient is ≥ 12 years of age; AND
- B) Patient has chronic graft-versus-host disease; AND
- C) Patient has tried at least two conventional systemic treatments for chronic graft-versus-host disease.

Note: Examples of systemic therapy may include methylprednisolone, Imbruvica® (ibrutinib capsules and tablets), cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil, imatinib.

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 365 days
- B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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Rezurock has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Rezurock tablets [prescribing information]. Warrendale, PA: Kadmon Pharmaceuticals; July 2021.
2. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 28, 2021. Search term: belumosudil.
3. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 1.2022 – April 1, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed September 7, 2022