Clinical Policy: Belumosudil (Rezurock)

Reference Number: CP.PHAR.552
Effective Date: 12.01.21
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Belumosudil (Rezurock®) is an inhibitor of rho-associated, coiled-coil containing protein kinase (ROCK).

FDA Approved Indication(s)

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Rezurock is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Graft-Versus-Host Disease (must meet all)**:**

1. Diagnosis of cGVHD;
2. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist;
3. Age ≥ 12 years;
4. Member has a history of allogenic hematopoietic cell transplant (HCT);
5. One of the following (a or b):
   a. For Illinois HIM requests only: Failure of two prior lines of systemic therapy (*see Appendix B for examples*), unless clinically significant adverse effects are experienced or all are contraindicated;
   b. For all other requests: Both of the following (i and ii):
      i. Failure of a systemic corticosteroid (*see Appendix B for examples*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      ii. Failure of a systemic non-steroidal immunosuppressant* (*see Appendix B for examples*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

   **Prior authorization may be required*
6. Rezurock is not prescribed concurrently with Imbruvica®, Jakafi®, or Niktimvo™;
7. Dose does not exceed 400 mg (2 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Rezurock for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Rezurock is not prescribed concurrently with Imbruvica, Jakafi, or Niktimvo;
4. If request is for a dose increase, new dose does not exceed 400 mg (2 tablets) per day;

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

cGVHD: chronic graft-versus-host disease
FDA: Food and Drug Administration
HCT: hematopoietic cell transplant
NCCN: National Comprehensive Cancer Network
ROCK: rho-associated, coiled-coil containing protein kinase

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of systemic corticosteroids and immunosuppressants for cGVHD		
Systemic corticosteroids (e.g., methylprednisolone, prednisone)	Varies	Varies
Imbruvica® (ibrutinib)		
Jakafi® (ruxolitinib)		
mycophenolate mofetil (Cellcept®)†		
cyclosporine (Gengraf®, Neoral®, Sandimmune®)†		
tacrolimus (Prograf®)†		
sirolimus (Rapamune®)†		
imatinib (Gleevec®)†		
rituximab (Riabni®, Rituxan®, Ruxience®, Truxima®)†		
Campath® (alemtuzumab)†		
Lemtrada® (alemtuxumab) †		
Enbrel® (etanercept)†		
Orencia® (abatacept) †		
Nipent™ (pentostatin)†		
hydroxychloroquine		
methotrexate, low-dose		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†*Off-label*

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
cGVHD	200 mg PO QD Strong CYP3A Inducers, Proton Pump Inhibitor: Increase Rezurock dosage to 200 mg PO BID.	400 mg/day

VI. Product Availability

Tablet: 200 mg

VII. References

1. Rezurock Prescribing Information. Warrendale, PA: Kadmon Pharmaceuticals, LLC; January 2026. Available at: https://products.sanofi.us/rezurock/rezurock.pdf. Accessed July 8, 2026.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 16, 2026.
3. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT) Version 3.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed August 16, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: no significant changes; added exclusion for concomitant use with Imbruvica or Jakafi into the Continued Therapy section, consistent with the approach in the Initial Approval Criteria section; references reviewed and updated. Template changes applied to other diagnoses/indications.	07.06.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	08.07.23	11.23
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.19.24	11.24
4Q 2025 annual review: added exclusion for concomitant use with Niktimvo; references reviewed and updated.	07.15.25	11.25
4Q 2026 annual review: clarified systemic immunosuppressant as non-steroidal; added step therapy bypass for IL HIM per IL HB 5395; added ICHRA line of business; references reviewed and updated.	07.08.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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