

## Clinical Policy: Belumosudil (Rezurock)

Reference Number: ERX.SPA.451

Effective Date: 12.01.21

Last Review Date: 11.21

Line of Business: Commercial, 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.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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  $\geq$  12 years;
4. Member has a history of allogenic hematopoietic cell transplant (HCT);
5. Failure of a systemic corticosteroid (*see Appendix B*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of a systemic immunosuppressant (*see Appendix B*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required*
7. Rezurock is not prescribed concurrently with Imbruvica® or Jakafi®;
8. Dose does not exceed 400 mg (2 tablets) per day;

**Approval duration: 6 months**

##### B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Rezurock is not prescribed concurrently with Imbruvica or Jakafi;
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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less);** or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. 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 policy – ERX.PA.01 or evidence of coverage documents.

**III. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ROCK: inhibitor of rho-associated, coiled-coil containing protein kinase      NCCN: National Comprehensive Cancer Network  
cGVHD: chronic graft-versus-host disease

FDA: Food and Drug Administration

*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
<b>Examples of systemic corticosteroids and immunosuppressants for cGVHD</b>		
Systemic corticosteroids (e.g., methylprednisolone, prednisone)	Varies	Varies
mycophenolate mofetil (Cellcept®)		
cyclosporine (Gengraf®, Neoral®, Sandimmune®)		
tacrolimus (Prograf®)		
sirolimus (Rapamune®)		
imatinib (Gleevec®)		
Imbruvica® (ibrutinib)		
Jakafi® (ruxolitinib)		

*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.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

**IV. Dosage and Administration**

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

**V. Product Availability**

Tablet: 200 mg

**VI. References**

1. Rezerock Prescribing Information. Warrendale, PA: Kadmon Pharmaceuticals, LLC; July 2021. Available at: <https://www.rezerock.com/>. Accessed August 10, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed August 10, 2021.

3. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT): Pre-Transplant Recipient Evaluation and Management of Graft-Versus-Host Disease Version 3.2021. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/hct.pdf](https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf). Accessed August 10, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.10.21	11.21

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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