Original Effective Date: 10/27/2021
Current Effective Date: 11/29/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C22106-A

Rezurock (belumosudil)

PRODUCTS AFFECTED

Rezurock (belumosudil)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic graft-versus-host disease (chronic GVHD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case- by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CHRONIC GRAFT VERSUS HOST DISEASE (GVHD):
   1. Documentation of diagnosis of chronic graft versus host disease
      AND
   2. Documentation member has previously received at least 2 systemic therapies for GVHD

(i.e., corticosteroids, mycophenolate, cyclosporine, tacrolimus, ruxolitinib)
AND

3. Prescriber attests that female members are not currently pregnant and have been advised of the potential risk to a fetus and to use effective contraception during treatment and one week after last dose OR male members with female partners of reproductive potential have been advised of the potential risk to a fetus and to use effective contraception during treatment and one week after last dose
AND
4. Documentation of baseline signs and symptoms (e.g., dry eyes, shortness of breath, rash, mouth sores, tingling sensation, muscle and joint pain, etc.) [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. CHRONIC GRAFT VERSUS HOST DISEASE (GVHD):
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., dry eyes, shortness of breath, rash, mouth sores, tingling sensation, muscle and joint pain, etc.) [DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified hematologist, oncologist, or transplant specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
200 mg given orally once daily, maximum of 30 tablets/30 days

For patients taking a strong CYP3A inducer (see Appendix) or a proton pump inhibitor, the dose of belumosudil should be increased to 200 mg twice daily. Maximum of 60 tablets/30 days for these members ONLY.

Maximum Quantity Limits – 200 mg given orally twice daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
ROCK Inhibitors

FDA-APPROVED USES:
Indicated for the 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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Cytochrome P450 3A (including 3A4) inducers

Strong inducers
Apalutamide
Carbamazepine
Enzalutamide
Fosphenytoin
Lumacaftor
Lumacaftor-ivacaftor
Mitotane
Phenobarbital
Phenytoin
Primidone
Rifampin (rifampicin)

Moderate inducers
Bexarotene
Bosentan
Cenobamate
Dabrafenib
Dexamethasone
Dipyrone
Efavirenz
Elagolix, estradiol, and norethindrone therapy pack
Eslicarbazepine
Etravirine
Lorlatinib
Modafinil
Nafcillin
Pexidartinib
Rifabutin
Rifapentine
Sotorasib
St. John's wort

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Graft-versus-host disease (GVHD) occurs when immune cells transplanted from a non-identical donor (the graft) recognize the transplant recipient (the host) as foreign, thereby initiating an immune reaction that causes disease in the transplant recipient. Chronic graft-versus-host disease (cGVHD) is the major determinant of long-term outcome and quality of life following allogeneic hematopoietic cell transplantation (HCT). Symptoms usually present within 3 years after allogeneic HCT and are often preceded by a history of acute GVHD. Manifestations of chronic GVHD may be restricted to a single organ or tissue or may be widespread. The primary manifestations of cGVHD are sclerotic cutaneous effects, dry oral mucosa, ulcerations and sclerosis of the gastrointestinal tract, and elevated serum bilirubin. Chronic GVHD can lead to debilitating consequences, e.g., joint contractures, loss of sight, end-stage lung disease, or mortality resulting from profound chronic immune suppression leading to recurrent or life-threatening infections. Approximately half of patients with cGVHD become steroid refractory (SR), which greatly increases the risk of poor outcomes.

Rezurock is the first and only FDA-approved rho-associated, coiled-coil containing protein kinase 2 (ROCK2) inhibitor. ROCK2 is a signaling pathway that modulates inflammatory response and fibrotic processes. By inhibiting ROCK2, Rezurock is thought to restore immune homeostasis and reduce fibrosis in affected organs. Rezurock was approved based on the results of the Phase 2 randomized, multicenter ROCKstar (NCT03640481) clinical trial, which enrolled patients ≥12 years of age with cGVHD who had received 2–5 previous lines of systemic therapy.
Patients were randomized (1:1) to receive 1 of 2 regimens: Rezurock 200 mg once daily (n = 66) or 200 mg twice daily (n = 66). The overall median follow-up for the ROCKstar study was 14 months. Rezurock was approved by the FDA based on the results of 65 patients who were treated with Rezurock 200 mg once daily as reflected in the package insert The primary end point was best overall response rate (ORR). Duration of response (DOR), changes in Lee Symptom Scale score, failure-free survival, corticosteroid dose reductions and overall survival were also evaluated. Overall median follow-up was 14 months. The best ORR (95% CI) of belumosudil 200 mg QD and 200 mg BID was 74% (62%-84%) and 77% (65%-87%), respectively, with high response rates observed in all subgroups. All affected organs demonstrated complete responses. The median DOR was 54 weeks; 44% of subjects have remained on therapy for ≥1 year. Symptom reduction with belumosudil 200 mg QD and 200 mg BID was reported in 59% and 62% of subjects, respectively. Adverse events (AEs) were consistent with those expected in patients with cGVHD receiving corticosteroids and other immunosuppressants. Sixteen subjects (12%) discontinued belumosudil due to possible drug-related AEs.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Rezurock (belumosudil) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Rezurock (belumosudil) include: None currently.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Rezurock TABS 200MG

REFERENCES

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8. National Comprehensive Cancer Network. 2023. Hematopoietic Cell Transplantation (HCT) (Version 1.2023). [online] Available at: < hct.pdf (nccn.org) > [Accessed 22 September 2023].

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Continuation of Therapy Appendix References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file