

Pharmacy Policy Bulletin

Title: Belumosudil (Rezurock™)

Policy #: Rx.01.256

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Belumosudil (Rezurock™)** as provided under the member's prescription drug benefit.

Description:

Graft-versus-host disease (GVHD) can develop after allogeneic hematopoietic cell transplant (HCT), when immune cells from a non-identical donor (the graft) initiate an immune reaction against a transplant recipient (the host). Chronic GVHD is a syndrome of variable clinical features that resembles autoimmune and other immunologic disorders (eg, scleroderma, Sjögren's syndrome, primary biliary cirrhosis, bronchiolitis obliterans). Clinical manifestations may be widespread, or they may be restricted to a single organ or site. The primary clinical manifestations are skin involvement (resembling lichen planus or cutaneous scleroderma), dry oral mucosa, gastrointestinal tract ulcerations and sclerosis, elevated serum bilirubin, and bronchiolitis obliterans. Chronic GVHD is a major cause of morbidity and mortality after allogeneic HCT, which worsen with increasing disease severity. Patients have impaired physical, social, and psychological well-being and impaired quality of life.

Belumosudil is an inhibitor of rho-associated, coiled-coil containing protein kinase (ROCK) which inhibits ROCK2 and ROCK1 with IC50 values of approximately 100 nM and 3 µM, respectively. Belumosudil down-regulated proinflammatory responses via regulation of STAT3/STAT5 phosphorylation and shifting Th17/Treg balance in ex-vivo or in vitro-human T cell assays. Belumosudil also inhibited aberrant pro-fibrotic signaling, in vitro. In vivo, belumosudil demonstrated activity in animal models of chronic GVHD.

REZUROCK is a kinase inhibitor 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.

Policy:

INITIAL CRITERIA Belumosudil (Rezurock™) is approved when ALL of the following are met:

- A. Diagnosis of chronic graft-versus-host disease; and
- B. Member is 12 years of age or older; and
- C. Inadequate response or inability to tolerate two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.); and
- D. Prescribed by or in consultation with one of the following:
 1. Hematologist; or
 2. Oncologist; or
 3. Physician experienced in the management of transplant patients

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Belumosudil (Rezurock™) is re-approved if member does not show evidence of progressive disease while on therapy

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Rezurock™ [package insert]. Warrendale, PA: Kadmon Pharmaceuticals. July 2021. Available at: <https://www.rezurock.com/full-prescribing-information.pdf>. Accessed October 03, 2022.

Zeiser R. Clinical manifestations and diagnosis of chronic graft-versus-host disease. UpToDate website. Last updated February 17, 2022. Available at <http://www.uptodate.com/>. Accessed October 03, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name

Rezurock™

Generic Name

Belumosudil

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:

2.00

P&T Approval Date:

September 15, 2022

Policy Effective Date:

January 01, 2023

Next Required Review Date:

September 15, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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