PRIOR AUTHORIZATION POLICY

POLICY: Immunosuppressive Agents – Rezurock Prior Authorization Policy
- Rezurock™ (belumosudil tablets – Kadmon)

REVIEW DATE: 08/21/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Rezurock, a kinase inhibitor, is indicated for the treatment of **chronic graft-versus-host disease** (GVHD) in patients ≥ 12 years of age after failure of at least two prior lines of systemic therapy.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) Hematopoietic Cell Transplantation (version 1.2024 – April 26, 2024) guidelines recommend Rezurock for chronic GVHD as additional therapy in conjunction with systemic corticosteroids following failure (steroid-refractory disease) to ≥ two prior lines of systemic therapy.[2,3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rezurock. All approvals are provided for the duration noted below.

- **Rezurock™ (belumosudil tablets (Kadmon)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Graft-Versus-Host Disease.** Approve for 1 year if the patient meets ALL of the following (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, tablets, or oral solution), cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil, imatinib.

Conditions Not Covered

- **Rezurock™ (belumosudil tablets (Kadmon)**

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

References

1. Rezurock™ tablets [prescribing information]. Warrendale, PA: Kadmon; April 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 13, 2024. Search term: belumosudil.
3. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 1.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 13, 2024.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/16/2023
Annual Revision	No criteria changes.	08/21/2024

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