Effective Date 08/01/2025
Coverage Policy Number IP0313

Belumosudil

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Related Coverage Resources

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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

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

Rezurock has been addressed in the National Comprehensive Cancer Network Hematopoietic Cell Transplantation guidelines (version 1.2025 – February 28, 2025). Options for first-line therapy for chronic GVHD including restarting, continuing, or escalating the original immunosuppressive agent(s) and/or administering systemic corticosteroids (0.5 to 1 mg/kg day of methylprednisolone or prednisone dose equivalent). Among the agents FDA-approved for use in chronic GVHD, Jakafi® (ruxolitinib tablets) is the only agent given a category 1 recommendation for chronic GVHD. Rezurock, Niktimvo™ (axatilimab-csfr intravenous infusion), and Imbruvica® (ibrutinib tablets, capsules, and oral suspension) each have a category 2A recommendation. The guidelines cite that each of these FDA-approved agents should be used following failure of one or two lines of systemic therapy (depending on the agent). Other medication alternatives include Orencia® (abatacept intravenous [IV] infusion and subcutaneous [SC] injection), Lemtrada® (alemtuzumab IV infusion), calcineurin inhibitors (e.g., tacrolimus,

cyclosporine), Enbrel® (etanercept SC injection), extracorporeal photopheresis, hydroxychloroquine, imatinib, Proleukin® (aldesleukin IV infusion and SC injection), low-dose methotrexate, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, pentostatin, and rituximab.

Coverage Policy

Belumosudil (Rezurock) is considered medically necessary when the following are met:

FDA Approved Indication

1. **Graft-Versus-Host Disease.** Individual meets **ALL** of the following criteria:
    A. Age 12 years or older
    B. Patient has chronic graft-versus-host disease
    C. Failure, contraindication, or intolerance to **TWO** conventional systemic treatments for chronic graft-versus-host disease (for example, methylprednisolone, Imbruvica® [ibrutinib], cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil, imatinib)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Belumosudil (Rezurock) is considered medically necessary for Graft-Versus-Host Disease when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Rezurock for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Rezurock® tablets [prescribing information]. Bridgewater, NJ: Kadmon; January 2024.
2. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 1.2025 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	No criteria changes	12/01/2024
Selected Revision	**Added** Individual and Family Plans to the policy. **Removed** documentation requirements.	08/01/2025

The policy effective date is in force until updated or retired.