Effective Date **12/1/2024**
Coverage Policy Number **IP0313**

Belumosudil

Table of Contents

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 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.

Overview

This policy supports medical necessity review for belumosudil (**Rezurock**™).

Medical Necessity Criteria

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

1. **Graft-Versus-Host Disease.** Individual meets **ALL** of the following criteria:
   A. Age 12 years or older
   B. Documented diagnosis of chronic graft-versus-host disease
   C. Documentation of 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

Conditions Not Covered

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

Background

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]

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.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	No criteria changes	12/1/2024

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