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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 13, 2021
Subject:	Rezurock	**Page:**	1 of 4

Last Review Date: March 8, 2024

Rezurock

Description

Rezurock (belumosudil)

Background
Rezurock (belumosudil) is an inhibitor of rho-associated, coiled-coil containing protein kinase (ROCK). Through inhibition of protein kinases ROCK1 and ROCK2, Rezurock down-regulates proinflammatory responses via regulation of STAT3/STAT5 phosphorylation and shifting Th17/Treg balance in T cell assays. In animal models, Rezurock demonstrated activity against chronic graft-versus-host disease (GVHD) (1).

Regulatory Status
FDA-approved indication: Rezurock is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy (1).

Rezurock can cause hepatotoxicity. Bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT) should be monitored at least monthly. In cases of severe AST, ALT, or bilirubin elevations, withhold, then resume at recommended dose, or permanently discontinue Rezurock (1).

Rezurock exposure was reduced when administered with either a proton pump inhibitor (PPI), or strong CYP3A inducer. Increase the dosage to 200 mg twice daily when coadministered with either a PPI or strong CYP3A inducer (1).

Rezurock can cause fetal harm when administered to pregnant women. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Rezurock and for at least one week after the last dose (1).

The safety and effectiveness of Rezurock in pediatric patients less than 12 years old have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rezurock may be considered **medically necessary** if the conditions indicated below are met.

Rezurock may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Chronic graft-versus-host disease (cGVHD)
    a. Patient has received at least two prior lines of systemic therapy

AND ALL of the following:

a. Prescriber agrees to monitor AST, ALT, and bilirubin at least monthly
b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Rezurock and for 1 week after the last dose
c. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Rezurock and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Chronic graft-versus-host disease (cGVHD)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor AST, ALT, and bilirubin at least monthly
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Rezurock and for 1 week after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Rezurock and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 180 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rezurock (belumosudil) is an orally administered kinase inhibitor indicated for the treatment of patients with chronic graft-versus-host disease who have received at least two prior lines of systemic treatment. Rezurock carries a warning for embryo-fetal toxicity. Coadministration with PPIs or strong CYP3A inducers has been found to reduce exposure of Rezurock and it is recommended to increase the dose in this context. The safety and effectiveness of Rezurock in pediatric patients less than 12 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Rezurock while maintaining optimal therapeutic outcomes.

References

1. Rezurock [package insert]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; November 2023.
2. NCCN Drugs & Biologics Compendium® Belumosudil 2024. National Comprehensive Cancer Network, Inc. Accessed on January 30, 2024.

Policy History

Date	Action
August 2021	Addition to PA
September 2021	Annual review and reference update
December 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.