BlueCross BlueShield
Federal Employee Program

REZUROCK
(belumosudil)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

Summary

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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; December 2024.
2. NCCN Drugs & Biologics Compendium® Belumosudil 2025. National Comprehensive Cancer Network, Inc. Accessed on January 23, 2025.