

Effective Date: 6/1/2023 Reviewed: 3/2023, 4/2024, 1/2025 Scope: Medicaid

REZUROCK (belumosudil)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Chronic Graft versus Host Disease (cGVHD)

Rezurock is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Chronic Graft versus Host Disease (cGVHD)

Authorization of 6 months may be granted for treatment of cGVHD when all of the following criteria are met:

- 1. The member is at least 12 years of age
- 2. The member has a documented diagnosis of cGVHD
- 3. The medication is prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients
- 4. The member has failed two or more lines of systemic therapy for chronic graft versus host disease (e.g. methylprednisolone, cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil, imatinib).
- 5. Rezurock will not be prescribed in combination with Imbruvica or Jakafi.
- 6. Documentation that Rezurock will not be taken concomitantly with a proton pump inhibitor (PPI) unless the member has previously experienced an inadequate treatment response or is contraindicated to treatment with a histamine H2-receptor antagonist (H2RA) at the highest appropriate dose.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when all of the following criteria are met:

- 1. The member does not have evidence of unacceptable toxicity while on the current regimen
- 2. The member has not experienced clinically significant progression of cGVHD (i.e., progression that requires new systemic therapy) while on the current regimen.
- 3. Rezurock will not be prescribed in combination with Imbruvica or Jakafi.



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4. Documentation that Rezurock will not be taken concomitantly with a proton pump inhibitor (PPI) unless the member has previously experienced an inadequate treatment response or is contraindicated to treatment with a histamine H2-receptor antagonist (H2RA) at the highest appropriate dose.

IV. QUANTITY LIMIT

Rezurock 200mg: 30 tablets per 30 days (1 tablet per day)

V. REFERENCES

1. Rezurock [package insert]. Warrendale, PA: Kadmon Pharmaceuticals; November 2023.