Clinical Policy Title:	belumosudil
Policy Number:	RxA.700
Drug(s) Applied:	Rezurock™
Original Policy Date:	08/19/2021
Last Review Date:	09/14/2021
,Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
belumosudil (Rezurock™)	cGVHD	200 mg taken orally once daily with food.	200 mg/day orally once daily

Dosage Forms

- Tablet: 200 mg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Chronic Graft-Versus-Host Disease (must meet all):

1. Diagnosis of cGVHD;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 12 years;
4. Member has a history of bone marrow/stem cell transplant;
5. Failure of at least two (2) systemic therapies (e.g. corticosteroids, immunosuppressants, alemtuzumab, dacluzimab, infliximab, antithymocyte globulin, Mesenchymal stem cells, pentostatin) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg per day;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (Prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Chronic Graft-Versus-Host Disease (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (Prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
cGVHD: Chronic graft-versus-host disease
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

APPENDIX B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Maximum Dose
Ibrutinib (Imbruvica®)	Treatment of marginal zone lymphoma in patients who require systemic therapy and have received at least 1 prior anti-CD20-baed therapy: 560 mg once daily. For treatment of cGVHD after failutre of 1 or more lines of systemic therapy: 420 mg once daily.	560 mg/day
ruxolitinib (Jakafi®)	Treatment of steroid-refractory acute GVHD: initially 5 mg orally twice daily. After 3 days, may increase to 10 mg twice daily if ANC and platelet counts are not decreased by at least 50%.	20 mg/day

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None

- Boxed Warning(s):
  - None

APPENDIX D: General Information

- Patients using concomitant proton pump inhibitors (PPIs) will require a twice-daily dose of Rezurock™, resulting in double the usual cost of therapy ($31,000 per 30-day supply or $372,000 per year). Consider requiring a trial of an H2 blocker (e.g. famotidine) or transitioning off of the PPI prior to starting Rezurock™.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

References

1. Rezurock™ Prescribing Information. Warrendale, PA: Kadmon Pharmaceuticals LLC; July 2021. Available at: https://rezurock.com/. Accessed August 19, 2021.
2. IPD Analytics Rx Insights_New Drug Approval Review_ Rezurock™_08_2021. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=rezurock. Accessed August 19, 2021.
3. Clinical Pharmacology. ClinicalKey. Tampa, FL: Elsevier, 2021. Available at: http://www.clinicalkey.com. Accessed August 19, 2021.
4. Rezurock™, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com . Accessed August 19, 2021.
5. Rezurock™. Micromedex Solutions. Truven Health Analtics Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed August 19, 2021.
6. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation. Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed August 19, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/19/2021	09/14/2021