Rezurock® (belumosudil)
(Oral)

Document Number: IC-0613

Last Review Date: 10/24/2022
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Dates Reviewed: 08/2021, 11/2021, 11/2022

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Rezurock 200 mg tablet: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 200 mg daily

III. Initial Approval Criteria [1]

Coverage for is provided for treatment of the following conditions:

- Patient is at least 12 years of age; **AND**

Universal Criteria [1]

- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with proton-pump inhibitors (PPIs), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.) or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Will not be used in combination with ibrutinib (subsequent therapy is allowed); **AND**

Chronic Graft versus Host Disease (cGVHD) † Φ [1-3]

- Patient is post-allogeneic stem cell transplant (generally 3 or more months after transplant); **AND**
- Patient does not have histologic relapse of underlying cancer or post-transplant lymphoproliferative disease; **AND**

- Patient has failed two or more previous lines of systemic therapy for the treatment of cGVHD (e.g., corticosteroids, immunosuppressants, etc.); **AND**
- Used in combination with stable doses of corticosteroid therapy for GVHD

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hepatotoxicity, etc.; **AND**
- Response to therapy with an improvement in one or more of the following:
  - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.)
  - Patient-reported symptoms (e.g., Lee Symptom Scale, etc.)

V. Dosage/Administration [1,3,7,21-23,25]

Indication	Dose
cGVHD	The recommended dose of Rezurock is 200 mg given orally once daily until progression of chronic GVHD that requires new systemic therapy.

VI. Billing Code/Availability Information

HCPCS Code:

- J7599 – Immunosuppressive drug, not otherwise classified

NDC:

- Rezurock 200 mg tablet: 79802-0200-xx

VII. References

1. Rezurock [package insert]. Warrendale, PA; Kadmon Pharm., Inc. July 2022. Accessed October 2022.
2. Cutler CS, Lee SJ, Arai S, et al. Belumosudil for Chronic Graft-versus-Host Disease (cGVHD) After 2 or More Prior Lines of Therapy: The ROCKstar Study. Blood. 2021 Jul 15. pii: blood.2021012021. doi: 10.1182/blood.2021012021. [Epub ahead of print]
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for belumosudil. National Comprehensive Cancer Network, 2022. The

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4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hematopoietic Cell Transplantation (HCT), Version 2.2022. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2022.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.09	Other complications of bone marrow transplant

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC