0Clinical Policy Title:	belumosudil
Policy Number:	RxA.700
Drug(s) Applied:	Rezurock®
Original Policy Date:	08/19/2021
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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, a hematologist or physician experienced in the management of transplant patients;
3. Age ≥ 12 years;
4. Trial and failure of at least two (2) systemic therapies (e.g. corticosteroids, immunosuppressants) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 400 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

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 the member has 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 400 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

References

1. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed May 30, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/19/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated trial and failure criteria from Trial and 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 to Trial and failure of at least two (2) systemic therapies (e.g. corticosteroids, immunosuppressants) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced. 2. Initial Approval Criteria, I.A.6: Updated to include new combination therapy criteria Rezurock™ is not prescribed concurrently with Imbruvica® or Jakafi®. 3. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Rezurock™ is not prescribed concurrently with Imbruvica® or Jakafi®. 4. References were reviewed and updated.	06/27/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.2: Updated to add provider criteria as physician experienced in the management of transplant patients. 2. Initial Approval Criteria I.A.4: Updated to remove that member has a history of bone marrow/stem cell transplant. 3. Initial Approval Criteria, Approval Duration for both commercial and Medicaid updated from 6 months to 12 months. 4. Initial Approval Criteria, I.A.6 and II.A.3: Updated to remove that Rezurock™ is not prescribed concurrently with Imbruvica® or Jakafi®. 1. References were reviewed and updated.	05/30/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023