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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

RETIRED
Effective Date: 04/11/2024

Aliqopa™ (copanlisib)

HCPCS: J9030, J9057

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by or in consultation with an oncologist
 - d. Must have failed at least two prior systemic treatments
 - e. Should not be used if treatment failure has occurred with Aliqopa or another PI3 kinase inhibitor

- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Continuation of therapy until unacceptable toxicity or disease progression

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Aliqopa is a kinase inhibitor indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

- The 2022 National Comprehensive Cancer Network (NCCN) B-cell lymphoma guidelines do not recommend use of Aliqopa following prior treatment failure with Aliqopa or another phosphatidylinositol 3-kinase inhibitor. Guidelines also recommend treatment continue until disease progression or unacceptable toxicity occurs.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

References:

1. Aliqopa [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; Feb 2022.
2. Das M. Copanlisib in heavily pretreated indolent lymphoma. *The Lancet*. 2017; 18: e650.
3. Dreyling M, Santoro A, Mollica L, et al. Phosphatidylinositol 3-kinase inhibition by copanlisib in relapsed or refractory indolent lymphoma. *J Clin Oncol*. 2017; 35: 3898 - 905.
4. Gopal AK, Kahl BS, de Vos S, et al. PI3K inhibition by idelalisib in patients with relapsed indolent lymphoma. *N Eng J Med*. 2014; 370: 1008 - 18.
5. National Comprehensive Cancer Network. B-cell lymphomas (Version 5.2022). 2022 July 12. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed on January 19, 2023.

Policy History												
#	Date	Change Description										
2.0	Effective Date: 04/11/2024	Policy is being retired as Aliqopa is being discontinued										
1.9	Effective Date: 04/06/2023	Updated approval length to allow for FDA recommended dosing for at least 60 days										
1.8	Effective Date: 10/06/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time										
1.7	Effective Date: 10/07/2021	Annual review of criteria was performed, no changes were made										
1.6	Effective Date: 12/01/2020	UM medical management system update for BCBS <table border="1" style="margin-left: 40px; width: 60%;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	Yes											
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1.5	Effective Date: 10/08/2020	Annual Review										
1.4	Effective Date: 01/01/2020	UM medical management system update for MAPPO and BCNA <table border="1" style="margin-left: 40px; width: 60%;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.3	Effective Date: 11/07/2019	Annual Review of Medical Policy										
1.2	Effective Date: 11/01/2018	Updated criteria per oncology vendor										

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1.1	Effective Date: 08/09/2018	UM medical management system update for BCN <table border="1" data-bbox="493 193 1370 399"> <thead> <tr> <th data-bbox="493 193 971 260">Line of Business</th> <th data-bbox="971 193 1370 260">PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td data-bbox="493 260 971 296">BCBS</td> <td data-bbox="971 260 1370 296">No</td> </tr> <tr> <td data-bbox="493 296 971 331">BCN</td> <td data-bbox="971 296 1370 331">Yes</td> </tr> <tr> <td data-bbox="493 331 971 367">MAPPO</td> <td data-bbox="971 331 1370 367">No</td> </tr> <tr> <td data-bbox="493 367 971 399">BCNA</td> <td data-bbox="971 367 1370 399">No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
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1.0	Effective Date: 11/09/2017	Preliminary Criteria										

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*