Aliqopa (copanlisib)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	
Aliqopa (copanlisib) vial for infusion	

APPROVAL CRITERIA

Requests for Aligopa (copanlisib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of one of the following:
 - A. Follicular lymphoma; OR
 - B. Splenic marginal zone lymphoma (NCCN 2A); OR
 - C. Nodal marginal zone lymphoma (NCCN 2A); OR
 - D. Extranodal marginal zone lymphoma of the stomach or of nongastric sites (NCCN 2A); OR
- II. Disease is relapsed, refractory, or progressive; AND
- III. Individual is using as third line of therapy or greater (Label, NCCN 2A); AND
- IV. Individual has not had previous treatment with another PI3-kinase inhibitor previously (e.g. idelalisib (Zydelig)).

Requests for Aliqopa (copanlisib) may not be approved for the following:

- I. Individual is requesting for any other indication, including but not limited to when the criteria above have not been met: **OR**
- II. Repeat treatment after the development of disease progression or unacceptable toxicity.

Key References:

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed October 10, 2023.
- 3. Dreyling M, Santoro A, Mollica L, et al. . Phosphatidylinositol 3-kinase inhibition by copanlisib in relapsed or refractory indolent lymphoma [published correction appears in J Clin Oncol. 2018;36(5):521]. J Clin Oncol. 2017;35(35):3898-3905.
- 4. Dreyling M, Panayiotidis P, Egyed M, et al. Efficacy of copanlisib monotherapy in patients with relapsed or refractory marginal zone lymphoma: subset analysis from the CHRONOS-1 trial [abstract]. Blood 2017; 130: Abstract 4053.
- 5. Panayiotidis P, Follows GA, Mollica L, et al. Efficacy and safety of copanlisib in patients with relapsed or refractory marginal zone lymphoma. *Blood Adv.* 2021;5(3):823-828. doi:10.1182/bloodadvances.2020002910.
- 6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- 8. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed October 10, 2023.
 - a. B-Cell Lymphomas. V6.2023. Revised October 10, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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