

Aliqopa™ (copanlisib) (Intravenous)

Document Number: IC-0321

Last Review Date: 10/30/2018

Date of Origin: 09/19/2017

Dates Reviewed: 09/2017, 07/2018, 10/2018

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Aliqopa 60 mg vial: 3 vials per 28 day supply

B. Max Units (per dose and over time) [Medical Benefit]:

- 60 billable units on Days 1, 8, & 15 of a 28-day cycle

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Follicular lymphoma (FL) †

- Patient aged 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient has relapsed, refractory or progressive disease; **AND**
- Patient has received at least two prior systemic therapies

† FDA-labeled indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: \geq Grade 3 infections, uncontrolled hyperglycemia, uncontrolled hypertension, non-infectious pneumonitis, $ANC < 0.5 \times 10^3$ cells/mm³, severe cutaneous reactions, etc.; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration

| Indication | Dose |
|---------------------|--|
| Follicular lymphoma | 60 mg administered as an intravenous infusion on Days 1, 8, and 15 of a 28-day cycle |

VI. Billing Code/Availability Information

JCode:

J9057 – Injection, copanlisib, 1 mg: 1 billable unit = 1 mg (effective 1/1/2019)

J9999 – Not otherwise classified, antineoplastic drugs

C9030 – Injection, copanlisib, 1 mg (inactive after 1/1/2019)

NDC:

Aliqopa 60 mg single-use vial: 50419-0385-xx

VII. References

1. Aliqopa [package insert]. Whippany, NJ; Bayer HealthCare Pharmaceuticals Inc.; September 2017. Accessed September 2018.
2. Dreyling, M., Santoro, A., Mollica, L., et al. (2017) COPANLISIB IN PATIENTS WITH RELAPSED OR REFRACTORY INDOLENT B-CELL LYMPHOMA (CHRONOS-1). *Hematological Oncology*, 35(S2): 119–120. doi: 10.1002/hon.2437_107.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Copanlisib. National Comprehensive Cancer Network, 2018. 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 September 2018.
4. Dreyling, M., Santoro, A., Mollica, L., et al. Updated Safety and Efficacy from the Copanlisib CHRONOS-1 Trial in Patients with Relapsed or Refractory Indolent B-Cell Lymphoma: Low Incidence of Late-Onset Severe Toxicities. *Blood*, 130(Suppl 1), 2777.
5. Martin Dreyling, Armando Santoro, Luigina Mollica, et al. Phosphatidylinositol 3-Kinase Inhibition by Copanlisib in Relapsed or Refractory Indolent Lymphoma. *J Clin Oncol* 2017; 35: 3898-3905.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|---|
| C82.00 | Follicular lymphoma grade I, unspecified site |
| C82.01 | Follicular lymphoma grade I, lymph nodes of head, face and neck |
| C82.02 | Follicular lymphoma, grade I, intrathoracic lymph nodes |
| C82.03 | Follicular lymphoma grade I, intra-abdominal lymph nodes |

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| C82.04 | Follicular lymphoma grade I, lymph nodes of axilla and upper limb |
| C82.05 | Follicular lymphoma grade I, lymph nodes of inguinal regional and lower limb |
| C82.06 | Follicular lymphoma grade I, intrapelvic lymph nodes |
| C82.07 | Follicular lymphoma grade I, spleen |
| C82.08 | Follicular lymphoma grade I, lymph nodes of multiple sites |
| C82.09 | Follicular lymphoma grade I, extranodal and solid organ sites |
| C82.10 | Follicular lymphoma grade II, unspecified site |
| C82.11 | Follicular lymphoma grade II, lymph nodes of head, face and neck |
| C82.12 | Follicular lymphoma, grade II, intrathoracic lymph nodes |
| C82.13 | Follicular lymphoma grade II, intra-abdominal lymph nodes |
| C82.14 | Follicular lymphoma grade II, lymph nodes of axilla and upper limb |
| C82.15 | Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb |
| C82.16 | Follicular lymphoma grade II, intrapelvic lymph nodes |
| C82.17 | Follicular lymphoma grade II, spleen |
| C82.18 | Follicular lymphoma grade II, lymph nodes of multiple sites |
| C82.19 | Follicular lymphoma grade II, extranodal and solid organ sites |
| C82.20 | Follicular lymphoma grade III, unspecified, unspecified site |
| C82.21 | Follicular lymphoma grade III, unspecified, lymph nodes of head, face and neck |
| C82.22 | Follicular lymphoma, grade III, unspecified, intrathoracic lymph nodes |
| C82.23 | Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes |
| C82.24 | Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb |
| C82.25 | Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb |
| C82.26 | Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes |
| C82.27 | Follicular lymphoma grade III, unspecified, spleen |
| C82.28 | Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites |
| C82.29 | Follicular lymphoma grade III, unspecified, extranodal and solid organ sites |
| C82.30 | Follicular lymphoma grade IIIa, unspecified site |
| C82.31 | Follicular lymphoma grade IIIa, lymph nodes of head, face and neck |
| C82.32 | Follicular lymphoma, grade IIIa, intrathoracic lymph nodes |
| C82.33 | Follicular lymphoma grade IIIa, intra-abdominal lymph nodes |
| C82.34 | Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb |
| C82.35 | Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb |
| C82.36 | Follicular lymphoma grade IIIa, intrapelvic lymph nodes |
| C82.37 | Follicular lymphoma grade IIIa, spleen |
| C82.38 | Follicular lymphoma grade IIIa, lymph nodes of multiple sites |
| C82.39 | Follicular lymphoma grade IIIa, extranodal and solid organ sites |
| C82.40 | Follicular lymphoma grade IIIb, unspecified site |
| C82.41 | Follicular lymphoma grade IIIb, lymph nodes of head, face and neck |
| C82.42 | Follicular lymphoma, grade IIIb, intrathoracic lymph nodes |

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| C82.43 | Follicular lymphoma grade IIIb, intra-abdominal lymph nodes |
| C82.44 | Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb |
| C82.45 | Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb |
| C82.46 | Follicular lymphoma grade IIIb, intrapelvic lymph nodes |
| C82.47 | Follicular lymphoma grade IIIb, spleen |
| C82.48 | Follicular lymphoma grade IIIb, lymph nodes of multiple sites |
| C82.49 | Follicular lymphoma grade IIIb, extranodal and solid organ sites |
| C82.50 | Diffuse follicle center lymphoma, unspecified site |
| C82.51 | Diffuse follicle center lymphoma, lymph nodes of head, face, and neck |
| C82.52 | Diffuse follicle center lymphoma, intrathoracic lymph nodes |
| C82.53 | Diffuse follicle center lymphoma, intra-abdominal lymph nodes |
| C82.54 | Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb |
| C82.55 | Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb |
| C82.56 | Diffuse follicle center lymphoma, intrapelvic lymph nodes |
| C82.57 | Diffuse follicle center lymphoma, spleen |
| C82.58 | Diffuse follicle center lymphoma, lymph nodes of multiple sites |
| C82.59 | Diffuse follicle center lymphoma, extranodal and solid organ sites |
| C82.60 | Cutaneous follicle center lymphoma, unspecified site |
| C82.61 | Cutaneous follicle center lymphoma, lymph nodes of head, face, and neck |
| C82.62 | Cutaneous follicle center lymphoma, intrathoracic lymph nodes |
| C82.63 | Cutaneous follicle center lymphoma, intra-abdominal lymph nodes |
| C82.64 | Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb |
| C82.65 | Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb |
| C82.66 | Cutaneous follicle center lymphoma, intrapelvic lymph nodes |
| C82.67 | Cutaneous follicle center lymphoma, spleen |
| C82.68 | Cutaneous follicle center lymphoma, lymph nodes of multiple sites |
| C82.69 | Cutaneous follicle center lymphoma, extranodal and solid organ sites |
| C82.80 | Other types of follicular lymphoma, unspecified site |
| C82.81 | Other types of follicular lymphoma, lymph nodes of head, face, and neck |
| C82.82 | Other types of follicular lymphoma, intrathoracic lymph nodes |
| C82.83 | Other types of follicular lymphoma, intra-abdominal lymph nodes |
| C82.84 | Other types of follicular lymphoma, lymph nodes of axilla and upper limb |
| C82.85 | Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb |
| C82.86 | Other types of follicular lymphoma, intrapelvic lymph nodes |
| C82.87 | Other types of follicular lymphoma, spleen |
| C82.88 | Other types of follicular lymphoma, lymph nodes of multiple sites |
| C82.89 | Other types of follicular lymphoma, extranodal and solid organ sites |
| C82.90 | Follicular lymphoma, unspecified, unspecified site |
| C82.91 | Follicular lymphoma, unspecified, lymph nodes of head, face and neck |

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| C82.92 | Follicular lymphoma, unspecified, intrathoracic lymph nodes |
| C82.93 | Follicular lymphoma, unspecified, intra-abdominal lymph nodes |
| C82.94 | Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb |
| C82.95 | Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb |
| C82.96 | Follicular lymphoma, unspecified, intrapelvic lymph nodes |
| C82.97 | Follicular lymphoma, unspecified, spleen |
| C82.98 | Follicular lymphoma, unspecified, lymph nodes of multiple sites |
| C82.99 | Follicular lymphoma, unspecified, extranodal and solid organ sites |

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) and Local Coverage Determinations (LCDs) 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):

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) |
| 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 |