

Medical Policy: ALIQOPA® (copanlisib)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.46	August 9, 2023	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Aliqopa (copanlisib): is a kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and works primarily through isoforms PI3K-alpha and PI3K-beta which are expressed in malignant B cells. The result may be tumor cell death via apoptosis and inhibition of proliferation of primary malignant B cell lines. Several important cell-signaling pathways are also inhibited by copanlisib, such as CXCR12 mediated chemotaxis of malignant B cells, B-cell receptor (BCR) signaling and NF-kappa-B signaling in lymphoma cell lines.

Length of Authorization

Coverage will be provided for six months and may be renewed

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 60 mg Days 1, 8, & 15 of a 28-day cycle

Guideline

1. Follicular Lymphoma

Aliqopa (copanlisib) may be considered medically necessary when all of the following criteria are met:

- A. Patient is 18 years of age or older; **AND**
- B. Patient has a diagnosis of relapsed follicular lymphoma (FL); **AND**
- C. Aliqopa (copanlisib) is being used as a single-agent; **AND**
- D. Patient has failed at least two prior therapies.

Coverage for Aliqopa (copanlisib) may be renewed when the following criteria are met:

1. Disease response; **AND**
2. 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.

Applicable Procedure Codes

Code	Description
J9057	Injection, copanlisib, 1mg

Applicable NDCs

Code	Description
50419-0385-01	Injection, copanlisib, 1 mg

ICD-10 Diagnoses

Code	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
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal region 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 site
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 site
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.20	Follicular lymphoma grade III, unspecified site
C82.21	Follicular lymphoma grade III, lymph nodes of head, face, and neck
C82.22	Follicular lymphoma grade III, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, spleen
C82.28	Follicular lymphoma grade III, lymph nodes of multiple site
C82.29	Follicular lymphoma grade III, 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 site
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
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 site
C82.49	Follicular lymphoma grade IIIb, 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 site
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
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 site
C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/9/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/18/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	12/30/2020	Annual Review – no policy changes
EmblemHealth & ConnectiCare	9/30/2019	Annual Review – no policy changes
EmblemHealth & ConnectiCare	12/3/2018	Added J9057 and removed J9999, C9399 from Applicable Procedure Codes.

References

1. Aliqopa PI prescribing information. Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ 2017. Revised December, 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2017.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2017.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2017.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2017