

Copanlisib

NDC CODE(S) 50419-0385-XX ALIQOPA 60MG Solution Reconstituted (BAYER HEALTHCARE PHARMA)

DESCRIPTION

Copanlisib is a kinase inhibitor for intravenous infusion and exhibits inhibitory activity predominantly against phosphatidylinositol-3-kinase PI3K- α and PI3K- δ isoforms expressed in malignant B cells. Copanlisib has been shown to induce tumor cell death by apoptosis and inhibition of proliferation of primary malignant B cell lines.

POLICY

- Copanlisib for the treatment of B-Cell Lymphoma is considered **medically necessary** if the medical appropriateness criteria are met. (See **Medical Appropriateness** below.)
- Copanlisib for the treatment of other conditions/diseases is considered **investigational**.

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Copanlisib is considered **medically appropriate** if **ALL** of the following criteria are met:
 - Individual is/has **ALL** of the following:
 - 18 years of age or older
 - Diagnosis of relapsed, refractory or progressive B-Cell Lymphoma
 - **No active infection, including clinically important localized infections**
 - Used as ALL of the following:
 - A single agent
 - **Subsequent therapy after** a minimum of two prior systemic therapies
 - Has **ANY ONE** of the following diagnoses:
 - Follicular lymphoma (FL)
 - Nongastric MALT Lymphoma (**Noncutaneous**)
 - Gastric MALT Lymphoma
 - Nodal Marginal Zone Lymphoma
 - Splenic Marginal Zone Lymphoma

RENEWAL CRITERIA

- Copanlisib is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
 - Individual continues to meet initial approval criteria, **not including prerequisite therapy**
 - Disease response to treatment as indicated by stabilization of disease or decrease in size of tumor or tumor spread
 - Absence of unacceptable toxicity from the agent (e.g., Grade 3 or greater infections, **pneumocystis Jiroveci pneumonia (PJP) of any grade**, uncontrolled hyperglycemia, uncontrolled hypertension, non-infectious pneumonitis, severe cutaneous reactions [**Grade 3 or life threatening**], **thrombocytopenia, neutropenia/ANC** < 0.5 x 10³ cells/mm³), etc.

INDICATION(S)	DOSAGE & ADMINISTRATION
B-Cell Lymphoma	60 mg administered as a 1-hour intravenous infusion on Days 1, 8 and 15 of a 28-day cycle

LENGTH OF AUTHORIZATION

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

Refer to **DOSAGE LIMITS** below

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

Lexicomp Online. (2020). AHFS DI. *Copanlisib*. Retrieved November 12, 2020 from Lexicomp Online with AHFS.

MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, August). *Copanlisib*. Retrieved November 12, 2020 from MICROMEDEX Healthcare Series.

National Comprehensive Cancer Network. (2020). NCCN Drugs & Biologics Compendium®. *Omacetaxine*. Retrieved November 12, 2020 from the National Comprehensive Cancer Network.

U. S. Food and Drug Administration. (2020, February). Center for Drug Evaluation and Research. *Aliqopa*® (*copanlisib*). Retrieved November 12, 2020 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209936s004lbl.pdf.

EFFECTIVE DATE 4/2/21

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