BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

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| **PHARMACY COVERAGE GUIDELINES** | |
| **SECTION: DRUGS** | |
| **ORIGINAL EFFECTIVE DATE:** | **2/21/2019** |
| **LAST REVIEW DATE:** | **2/17/2022** |
| **LAST CRITERIA REVISION DATE:** | **2/17/2022** |
| **ARCHIVE DATE:** | |

# COPIKTRA™ (duvelisib) oral capsule

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

# COPIKTRA™ (duvelisib) oral capsule

**Criteria**:

- **Criteria for initial therapy:** Copiktra (duvelisib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies

     b. Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies

     c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. Individual is on prophylaxis for *Pneumocystis jiroveci* during treatment

  5. **ALL** of the following baseline tests have been completed before initiation of treatment:
     a. Negative pregnancy test in a woman of reproductive potential
     b. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1

  6. There are no significant interacting drugs

  **Initial approval duration**: 6 months

- **Criteria for continuation of coverage (renewal request):** Copiktra (duvelisib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. Documented evidence of efficacy, disease stability and/or improvement
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

  3. Individual has been adherent with the medication

  4. Requested dose is at least 15 mg twice daily

# COPIKTRA™ (duvelisib) oral capsule

5. Individual is on prophylaxis for *Pneumocystis jiroveci* during treatment

6. Individual has not developed any significant adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Recurrent or severe or life-threatening diarrhea
        ii. Recurrent or severe or life-threatening colitis
        iii. Recurrent, worsening, or nonresponsive severe cutaneous reactions or first occurrence of life-threatening cutaneous reactions
        iv. First occurrence of Stevens-Johnson Syndrome, toxic epidermal necrolysis, or drug rash with eosinophilia and systemic symptoms (DRESS)
        v. Recurrent or nonresponsive symptomatic moderate pneumonitis or first occurrence of severe or life-threatening pneumonitis
        vi. *Pneumocystis jiroveci* infection
        vii. ALT/AST elevation > 20 x upper limit of normal

7. There are no significant interacting drugs

**Renewal duration**: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-cancer Medications**

    2. **Off-Label Use of Cancer Medications**

**Description:**

Copiktra (duvelisib) indicated for the treatment of adult patients with: a) relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies and b) relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials

Copiktra (duvelisib) is a dual inhibitor of phosphatidylinositol 3-kinases PI3K-δ and PI3K-γ. Duvelisib induced growth inhibition and reduced viability in cell lines derived from malignant B-cells and in primary CLL tumor cells. Duvelisib inhibits several key cell-signaling pathways, including B-cell receptor signaling and CXCR12-mediated chemotaxis of malignant B-cells.

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**Resources:**

Copiktra (duvelisib) product information, revised by Verastem, Inc. 07-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 06, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): B-Cell Lymphomas Version 5.2021 – Updated September 22,2021. Available at https://www.nccn.org. Accessed December 02, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 1.2022 – Updated September 08, 2021. Available at https://www.nccn.org. Accessed December 02, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.