



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 2/21/2019
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/13/2020
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.

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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.**



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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. Individual is on prophylactic antiviral therapy for cytomegalovirus
 6. **ALL** of the following baseline tests have been completed before initiation of treatment:
 - a. Complete blood count
 - b. Liver function tests
 - c. Negative pregnancy test in a woman of reproductive potential

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 not worsened while on therapy
 3. Individual has been adherent with the medication
 4. Individual is on prophylaxis for *Pneumocystis jiroveci* during treatment
 5. Individual is on prophylactic antiviral therapy for cytomegalovirus
 6. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use



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- a. Significant adverse effect such as:
 - i. Recurrent or severe or life-threatening diarrhea
 - ii. Recurrent or severe or life-threatening colitis
 - iii. Severe or life-threatening cutaneous reactions
 - iv. Severe or life-threatening pneumonitis
 - v. *Pneumocystis jiroveci* infection
 - vi. Cytomegalovirus reactivation or infection
 - vii. ALT/AST elevation > 20 x upper limit of normal

7. There are no significant interacting drugs

Renewal duration: 6 months

Description:

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.

Resources:

Copiktra (duvelisib) product information, revised by Verastem, Inc. 07-2019, at DailyMed
<http://dailymed.nlm.nih.gov>. Accessed January 30, 2021.

Copiktra (duvelisib). National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021; Available at: <http://www.nccn.org>. Accessed January 30, 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.
