UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Copiktra

Program	Prior Authorization
Medication	Copiktra® (duvelisib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	11/2018
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Copiktra® (duvelisib) is a kinase inhibitor indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. Copiktra is also indicated for the treatment of relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. The National Cancer Comprehensive Network (NCCN) also recommends the use of Copiktra for the treatment of gastric and nongastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma.

2. Coverage Criteria:

A. <u>Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)</u>

1. <u>Initial Authorization</u>

a. Copiktra will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

-AND-

(2) Disease is relapsed or refractory

-AND-

(3) History of failure, contraindication, or intolerance to at least **<u>two</u>** prior therapies for CLL/SLL. Examples include, but not limited to, regimens

consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.].

Authorization will be issued for 12 months.

2. Reauthorization

a. Copiktra will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Copiktra therapy

Authorization will be issued for 12 months.

B. B-cell lymphomas

1. Initial Authorization

a. Copiktra will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Follicular lymphoma
(b) Gastric MALT lymphoma
(c) Nodal marginal zone lymphoma
(d) Nongastric MALT lymphoma
(e) Splenic marginal zone lymphoma

-AND-

(2) Disease is relapsed or refractory

-AND-

(3) History of failure, contraindication, or intolerance to at least **two** prior systemic therapies (Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Rituxan (rituximab), Revlimid (lenalidomide) etc.])

Authorization will be issued for 12 months.

2. Reauthorization

a. Copiktra will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Copiktra therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Copiktra** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Copiktra** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Copiktra therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Copiktra [package insert]. Needham, MA: Verastem, Inc.; July 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp . Accessed on September 30, 2020.

Program	Prior Authorization - Copiktra (duvelisib)
Change Control	
Date	Change

11/2018	New program
11/2019	Annual review. Added coverage for additional B-cell lymphomas. Updated background and references.
11/2020	Annual review. Added additional first line NCCN treatment examples. No change to clinical criteria. Updated references. Added Additional Clinical Rules section.