VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Copiktra Prior Authorization Policy
- Copiktra® (duvelisib capsules – Secura Bio)

REVIEW DATE: 11/10/2021

OVERVIEW

Copiktra, a kinase inhibitor, is indicated for the treatment of adults for relapsed or refractory c**hronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)** after at least two prior therapies.

Guidelines

Copiktra is discussed in guidelines from the National Comprehensive Cancer Network (NCCN).

- **B-Cell Lymphoma:** The NCCN guidelines (version 5.2021 – September 22, 2021) recommend Copiktra as third line and subsequent therapy in patients with follicular lymphoma (Grade 1 to 2) who have relapsed or have refractory disease after two prior therapies (category 2A).[2] The guidelines recommend Copiktra as second-line and subsequent therapy for marginal zone lymphoma that has relapsed or is refractory to two prior therapies.[2]
- **CLL/SLL:** The NCCN guidelines (version 1.2022 – September 8, 2021) include Copiktra as one of several therapies for second-line and subsequent use as other recommended regimens (category 2A).[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Copiktra. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Copiktra is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Chronic Lymphocytic Leukemia.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried two systemic regimens.
   Note: Examples of systemic regimens include one or more of the following products: Imbruvica (ibrutinib capsules and tablets); Venclexta (venetoclax tablets); rituximab; Gazyva (obinutuzumab intravenous infusion); chlorambucil; fludarabine; cyclophosphamide; bendamustine; high-dose methylprednisolone; Campath (alemtuzumab intravenous infusion); Calquence (acalabrutinib capsules); Brukinsa (zanubrutinib capsules).

2. **Small Lymphocytic Lymphoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND

B) Patient has tried two systemic regimens.
Note: Examples of systemic regimens include one or more of the following products: Imbruvica (ibrutinib capsules and tablets); Venclexta (venetoclax tablets); rituximab; Gazyva (obinutuzumab intravenous infusion); chlorambucil; fludarabine; cyclophosphamide; bendamustine; high-dose methylprednisolone; Campath (alemtuzumab intravenous infusion); Calquence (acalabrutinib capsules); Brukinsa (zanubrutinib capsules).

Other Uses with Supportive Evidence

3. Follicular Lymphoma. Approve for 3 years if the patient meets the following criteria (A and B):
A) Patient is ≥ 18 years of age; AND
B) Patient has tried two systemic regimens.
Note: Examples of systemic regimens include one or more of the following products: bendamustine; rituximab; Gazyva (obinutuzumab intravenous infusion); cyclophosphamide; doxorubicin; vincristine; prednisone; chlorambucil; Revlimid (lenalidomide capsules).

4. Marginal Zone Lymphoma. Approve for 3 years if the patient meets the following criteria (A and B):
Note: Marginal zone lymphoma includes gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma.
A) Patient is ≥ 18 years of age; AND
B) Patient has tried two systemic regimens.
Note: Examples of systemic regimens include one or more of the following products: rituximab; bendamustine; cyclophosphamide; doxorubicin; vincristine; prednisone; chlorambucil; Imbruvica (ibrutinib tablets and capsules); Revlimid (lenalidomide capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Copiktra is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Copiktra® capsules [prescribing information]. Las Vegas, NV: Secura Bio; December 2021.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2021 – September 22, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 5, 2021.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2022 – September 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 5, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/04/2020
Annual Revision	**Chronic Lymphocytic Leukemia:** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient has tried "two prior therapies" was reworded to "two systemic regimens." **Follicular Lymphoma:** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient has tried "two prior therapies" was reworded to "two systemic regimens." **Small Lymphocytic Lymphoma:** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient has tried "two prior therapies" was reworded to "two systemic regimens." **MALT Lymphoma (Gastric and Nongastric):** This condition of approval was combined with the Marginal Zone Lymphoma condition for approval, and a note was added to the Marginal Zone Lymphoma condition of approval, "Marginal zone lymphoma includes gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma." **Marginal Zone Lymphoma:** A requirement was added that the patient is ≥ 18 years of age. A Note was added with the types of marginal zone lymphoma. The requirement that the patient has tried "two other therapies" was reworded to "two systemic regimens."	11/10/2021
Update	**02/21/2022**: **Follicular Lymphoma:** Condition of approval and criteria were moved from FDA-approved indications into Other Uses with Supportive Evidence due to change in FDA-labeling.	N/A