PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/16/2022

OVERVIEW

Copiktra, a phosphatidylinositol 3-kinase (PI3K) inhibitor, is indicated for the treatment of adults for relapsed or refractory **chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)** after at least two prior therapies.[1]

Guidelines

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

- **CLL/SLL:** NCCN guidelines (version 1.2023 – August 30, 2022) include Copiktra as subsequent therapy for relapsed or refractory disease after prior Bruton tyrosine kinase inhibitor and Venclexta (venetoclax tablets) based regimen in patients without deletion (del)[17p]/TP53 mutation. Copiktra is also recommended as second-line and subsequent therapy for del(17p)/TP53 mutation as other recommended regimens (category 2A).[2]
- **T-Cell Lymphoma:** NCCN guidelines (version 2.2022 – March 7, 2022) recommend Copiktra as second-line or initial palliative intent therapy and subsequent therapy for peripheral T-cell lymphoma; as second-line and subsequent therapy for relapsed/refractory disease for breast implant-associated anaplastic large cell lymphoma; and for hepatosplenic T-cell lymphoma as a single agent for refractory disease after two first-line therapy regimens.[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 1 year 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 1 year 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. **T-Cell Lymphoma**. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed or refractory disease; AND
   C) Patient has one of the following types of T-cell lymphoma (i, ii, or iii):
      i. Peripheral T-cell lymphoma; OR
      ii. Breast implant-associated anaplastic large cell lymphoma; OR
      iii. Hepatosplenic T-cell lymphoma.

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 Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – August 30, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 10, 2022.
3. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2022 – March 7, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 10, 2022.