Reference number(s)
2754-A

Standard Guideline Management
Copiktra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Copiktra	duvelisib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

Copiktra is indicated for the treatment of adult patients with relapsed or refractory CLL or SLL after at least two prior therapies.

Limitations of Use: Copiktra is not indicated or recommended for the treatment of any patients with CLL or SLL as initial or second line treatment due to an increased risk of treatment-related mortality.

Compendial Uses

- Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)
- T-Cell lymphomas
    - Breast implant associated anaplastic large cell lymphoma (ALCL)
    - Hepatosplenic T-Cell lymphoma
    - Peripheral T-cell lymphomas (PTCL)

All other indications are considered experimental/investigational and not medically necessary.

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Coverage Criteria

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

Authorization of 12 months may be granted for treatment of relapsed or refractory CLL/SLL when all of the following criteria are met:

- The member has received prior therapy with Bruton tyrosine kinase (BTKi) inhibitor (e.g., Brukinsa, Calquence) and venetoclax-based regimens
- The requested drug is used as a single agent.

T-Cell Lymphomas

Authorization of 12 months may be granted for treatment of T-cell lymphomas with any of the following subtypes:

- Breast implant-associated anaplastic large cell lymphoma (ALCL) when all of the following are met:
  - The requested drug is used as subsequent therapy for relapsed or refractory disease.
  - The requested drug is used as a single agent
- Hepatosplenic T-Cell lymphoma when all of the following criteria are met:
  - The requested drug is used for refractory disease after 2 first-line therapy regimens
  - The requested drug is used as a single agent
- Peripheral T-cell lymphoma (PTCL) [including the following subtypes: peripheral T-cell lymphoma not otherwise specified, enteropathy-associated T-cell lymphoma (EATL), monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL), angioimmunoblastic T-cell lymphoma (AITL), nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH), follicular T-cell lymphoma (FTCL), or anaplastic large cell lymphoma (ALCL) when all of the following criteria are met:
  - The requested drug is used as palliative or subsequent therapy for relapsed or refractory disease
  - The requested drug is used as a single agent

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Copiktra [package insert]. Las Vegas, NV: Secura Bio, Inc.; December 2021.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed June 2, 2024.