Reference number(s)
2754-A

SPECIALTY GUIDELINE MANAGEMENT

COPIKTRA (duvelisib)

POLICY

I. 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.

A. FDA-Approved Indications
1. 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.

2. Follicular lymphoma
   Copiktra is indicated for the treatment of adult patients with relapsed or refractory FL after at least two prior systemic therapies.

B. Compendial Use
1. Chronic lymphocytic leukemia/small lymphocytic lymphoma, preferred therapy as a single agent for relapsed or refractory disease with or without del(17p)/TP53 mutation
2. Gastric MALT lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies
3. Non-gastric MALT lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies
4. Nodal marginal zone lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies
5. Splenic marginal zone lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies
6. T-Cell lymphomas
   a. Breast implant associated anaplastic large cell lymphoma (ALCL)
   b. Hepatosplenic T-Cell lymphoma
   c. Peripheral T-cell lymphomas (PTCL)

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

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
Authorization of 12 months may be granted for treatment of relapsed or refractory CLL/SLL when the requested medication is used as single agent.

B. Follicular lymphoma (FL)
Authorization of 12 months may be granted for treatment of FL when the requested medication will be used as subsequent therapy after at least two prior therapies.

C. Gastric MALT Lymphoma and Non-gastric MALT Lymphoma
Authorization of 12 months may be granted for treatment of gastric or non-gastric MALT lymphoma when the requested medication will be used as subsequent therapy after at least two prior therapies.

D. Nodal Marginal Zone Lymphoma
Authorization of 12 months may be granted for treatment of nodal marginal zone lymphoma when the requested medication will be used as subsequent therapy after at least two prior therapies.

E. Splenic Marginal Zone Lymphoma
Authorization of 12 months may be granted for treatment of splenic marginal zone lymphoma when the requested medication will be used as subsequent therapy after at least two prior therapies.

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

1. Breast implant-associated anaplastic large cell lymphoma (ALCL) when all of the following are met:
   i. The requested drug is used as subsequent therapy for relapsed or refractory disease.
   ii. The requested drug is used as a single agent
2. Hepatosplenic T-Cell lymphoma when all of the following criteria are met:
   i. The requested drug is used for refractory disease after 2 first-line therapy regimens
   ii. The requested drug is used as a single agent
3. 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, or anaplastic large cell lymphoma (ALCL) when all of the following criteria are met:
   i. The requested drug is used as palliative or subsequent therapy for relapsed or refractory disease
   ii. The requested drug is used as a single agent

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Copiktra [package insert]. Needham, MA: Verastem, Inc.; July 2019.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed January 6, 2022.