Copiktra (duvelisib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Copiktra (duvelisib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Copiktra (duvelisib) may be approved if the following criteria are met:

I. Individual has a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); **AND**
II. Individual has used at least two prior therapies;

OR

III. Individual has a diagnosis of relapsed or refractory Peripheral T-cell Lymphoma (NCCN 2A);

OR

IV. Individual has a diagnosis of relapsed or refractory Breast Implant-Associated Anaplastic Large Cell Lymphoma (NCCN 2A);

OR

V. Individual has a diagnosis of Hepatosplenic T-cell Lymphoma and has refractory disease after two prior first-line therapy regimens (NCCN 2A).

Requests for Copiktra (duvelisib) may not be approved for the following:

I. Individual has had previous treatment with another PI3-kinase inhibitor (e.g. idelalisib, copanlisib).

Note:
Copiktra (duvelisib) has a black box warning for fatal and serious toxicities including infections, diarrhea, or colitis, cutaneous reactions, and pneumonitis. Fatal and/or serious infections, diarrhea or colitis, cutaneous reactions, or pneumonitis occurred in Copiktra-treated patients. Monitor for signs and symptoms and withhold if needed.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 10, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Brammer JE, Zinzani PL, Zain J, et al. Duvelisib in Patients with Relapsed/Refractory Peripheral T-cell Lymphoma from the Phase 2 Primo Trial: Results of an Interim Analysis [abstract] Blood 2021; 138; Abstract 2456.
5. Flinn IW, Miller CB, Ardeshna KM, et al. DYNAMO: A Phase II Study of Duvelisib (IPI-145) in Patients with Refractory Indolent Non-Hodgkin Lymphoma. J Clin Oncol 2019:11;912-922.
6. Flinn IW, Hillmen P, Montillo M, et al. The Phase 3 DUO trial: duvelisib vs ofatumumab in relapsed and refractory CLL/SLL. Blood 2018; 132:2446-2455.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 10, 2022.
    a. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V1.2023. Revised August 30, 2022.
    b. B-Cell Lymphomas. V5.2022. Revised July 12, 2022

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.