Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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

Initial 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
   A. Follicular lymphoma; **OR**
   B. MALT lymphoma (NCCN 2A); **OR**
   C. Nodal or Splenic Marginal Zone Lymphoma (NCCN 2A);

   AND
IV. Individual has previously used at least two prior systemic therapies.

Requests for continuation of therapy with Copiktra (duvelisib) may be approved if the following criteria is met:

I. Confirmation of continuing clinical benefit (e.g. complete response, partial response, or stable disease).

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:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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.: 2019. 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 2, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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.
5. 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.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 2, 2019.
    a. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V1.2020. Revised August 23, 2019.
    b. B-Cell Lymphomas. V5.2019. Revised September 23, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.