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

Zydelig (idelalisib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial: 6 months Maintenance: 6 months

Medications	Quantity Limit
Zydelig (idelalisib)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Zydelig (idelalisib) may be approved if the following criteria are met:

I. Individual has a diagnosis of relapsed/refractory/progressive chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL);

OR

II. Individual has a diagnosis of relapsed/refractory/progressive:
   A. Follicular lymphoma; **OR**
   B. MALT Lymphoma (NCCN 2A); **OR**
   C. Nodal or Splenic Marginal Zone Lymphoma (NCCN 2A);

AND

III. Individual has previously received at least 2 prior therapies.

Requests for continuation of therapy with Zydelig (idelalisib) may be approved if the following criteria are met:

I. Individual has achieved and sustained continuing clinical benefit (e.g. complete response, partial response, or stable disease); **AND**
II. Results are confirmed.

Zydelig (idelalisib) may **not** be approved for the following:

I. Individual is using for first-line treatment; **OR**
II. Individual is using in combination with bendamustine and/or rituximab for the treatment of follicular lymphoma; **OR**
III. Individual has had a previous treatment with another PI3-kinase inhibitor (e.g. duvelisib, copanlisib).

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

Note:
Zydelig (idelalisib) labeling includes black box warnings for hepatotoxicity, severe diarrhea, colitis, infections, pneumonitis and intestinal perforation. Fatal and/or serious hepatotoxicity, infections, diarrhea or colitis, pneumonitis occurred in Zydelig-treated individuals. Monitor and interrupt, reduce dose, or discontinue if needed. Fatal and serious intestinal perforation can occur; discontinue if this occurs.

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. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. 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.