

Zydelig (idelalisib)

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

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

APPROVAL CRITERIA

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

- I. Individual has a diagnosis of relapsed/refractory chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL); **AND**
- II. Individual is using Zydelig (idelalisib) as second line or subsequent therapy as a single agent or in combination with rituximab (Label, NCCN 2A).

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 a history of toxic epidermal necrolysis with any drug; **OR**
- IV. Individual has had a previous treatment with another PI3-kinase inhibitor (e.g. duvelisib, copanlisib).

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.: 2023. 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, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 10, 2023.
 - a. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V3.2023. Revised June 12, 2023.

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

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