

Reference number(s)
1706-A

# SPECIALTY GUIDELINE MANAGEMENT

## ZYDELIG (idelalisib)

### 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

Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities

##### *Limitations of use:*

*Zydelig is not indicated and is not recommended for first-line treatment of any patient, including patients with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and other indolent non-Hodgkin lymphomas.*

*Zydelig is not indicated and is not recommended in combination with bendamustine and rituximab, or in combination with rituximab for the treatment of patients with FL, SLL, and other indolent non-Hodgkin lymphomas.*

##### B. Compendial Uses

Relapsed or refractory CLL/SLL

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

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)**

Authorization of 12 months may be granted for treatment of relapsed or refractory CLL/SLL when either of the following criteria are met:

1. The requested drug will be used as a single agent, or
2. The requested drug will be used in combination with rituximab.

#### 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. Zydelig [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2022.

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2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 2, 2023.