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
1. 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
2. Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies
3. Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies

Limitations of use:
Zydelig is not indicated and is not recommended for first-line treatment of any patient.
Zydelig is not indicated and is not recommended in combination with bendamustine and/or rituximab for the treatment of FL.

B. Compendial Uses
1. Relapsed or refractory CLL/SLL
2. Refractory or relapsed follicular lymphoma
3. Marginal zone lymphomas (nodal, splenic, gastric mucosa-associated lymphoid tissue (MALT) and non-gastric MALT)

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

II. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. Follicular B-cell non-Hodgkin lymphoma (FL)
Authorization of 12 months may be granted for treatment of FL in patients who have received at least two prior systemic therapies for their disease.

C. Marginal zone lymphomas

Authorization of 12 months may be granted for treatment of marginal zone lymphoma (nodal, splenic, gastric mucosa-associated lymphoid tissue (MALT), and non-gastric MALT) in patients who have received at least two prior systemic therapies for their disease.

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.; October 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 14, 2021.