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.

Accelerated approval for FL and SLL was granted based on overall response rate. Improvement in patient survival or disease related symptoms has not been established. Continued approval for these indications may be contingent upon verification of clinical benefit in confirmatory trials.

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
Authorization of 12 months may be granted for treatment CLL/SLL when either of the following criteria are met:
a. Zydelig will be used as a single agent, or
b. Zydelig 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 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 who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES

1. Zydelig [package insert]. Foster City, CA: Gilead Sciences, Inc.; January 2018.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 28, 2019.