CareFirst Family of health care plans

CVS caremark™

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.

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 progressive follicular lymphoma
3. Marginal zone lymphomas (nodal, splenic, MALT)
4. Primary cutaneous B-cell lymphomas

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.

B. Follicular B-cell non-Hodgkin lymphoma (FL)
Authorization of 12 months may be granted for treatment of FL.

C. Marginal zone lymphomas
Authorization of 12 months may be granted for treatment of marginal zone lymphoma (nodal, splenic, MALT).

D. Primary cutaneous B-cell lymphoma
Authorization of 12 months may be granted for treatment of primary cutaneous B-cell lymphoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Zydelig [package insert]. Foster City, CA: Gilead Sciences, Inc.; September 2016.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2017.