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)
2. Relapsed Follicular B-cell non-Hodgkin Lymphoma (FL)
3. Relapsed Small Lymphocytic Lymphoma (SLL)

Accelerated approval for FL and SLL was granted based on overall response rate. An 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. Primary cutaneous B-cell lymphoma
    a. Primary cutaneous marginal zone lymphoma
    b. Follicle center lymphoma
4. Marginal zone lymphomas
    a. Recurrent or progressive gastric mucosa associated lymphoid tissue (MALT) lymphoma
    b. Refractory or progressive non-gastric MALT lymphoma
    c. Refractory or progressive splenic marginal zone lymphoma

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 Leukemia (SLL)

Authorization of 12 months may be granted to members who are prescribed Zydelig as a single agent or in combination with rituximab for the treatment of relapsed or refractory CLL/SLL.

B. Follicular B-cell non-Hodgkin Lymphoma (FL)

Authorization of 12 months may be granted for the treatment of relapsed, refractory, or progressive FL.

C. Marginal Zone Lymphomas (Gastric MALT Lymphoma, Non-gastric MALT Lymphoma, and Splenic Marginal Zone Lymphoma)

Authorization of 12 months may be granted for the treatment of ANY of the following marginal zone lymphomas:
a. Recurrent or progressive gastric MALT lymphoma
b. Refractory or progressive non-gastric MALT lymphoma
c. Refractory or progressive Splenic marginal zone lymphoma

D. Primary cutaneous B-cell Lymphoma

Authorization of 12 months may be granted for the treatment of ANY of the following primary cutaneous B-cell lymphoma subtypes:

a. Primary cutaneous marginal zone lymphoma
b. Follicle center lymphoma

III. CONTINUATION OF THERAPY

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

IV. DOSAGE AND ADMINISTRATIOM

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 300 mg per day

V. REFERENCES

1. Zydelig [package insert]. Foster City, CA: Gilead Sciences, Inc.; July 2014.
2. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 28, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Non-Hodgkin's Lymphomas. Version 2.2016. http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf. Accessed March 28, 2016.