UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zydelig

Program	Prior Authorization
Medication	Zydelig® (idelalisib)
Issue Date	10/2014
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Zydelig (idelalisib) is indicated for the treatment of patients with:[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.
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

Additionally, the National Cancer Comprehensive Network (NCCN) recommends use of Zydelig in treatment of gastric and nongastric MALT lymphomas, primary cutaneous B-cell lymphomas, splenic marginal zone lymphoma, and nodal marginal zone lymphoma.[2]

2. Coverage Criteria:

A. Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)

1. Initial Authorization

a. Zydelig will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Chronic Lymphocytic Leukemia (CLL)
(b) Small Lymphocytic Lymphoma (SLL)

-AND-

(2) **One** of the following:

(a) Disease has relapsed
(b) Disease is refractory

Authorization will be issued for 12 months.

2. Reauthorization

a. Zydelig will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zydelig therapy

Authorization will be issued for 12 months.

B. Non-Hodgkin Lymphoma (NHL)

1. Initial Authorization

a. Zydelig will be approved based on the following criteria:

(1) **Both** of the following:

(a) Diagnosis of **one** of the following:

i. Follicular lymphoma (FL)
ii. Gastric MALT Lymphoma
iii. Nongastric MALT Lymphoma
iv. Splenic Marginal Zone Lymphoma
v. Extracutaneous B-cell lymphoma
vi. Nodal Marginal Zone Lymphoma

-AND-

(b) Not used as first-line therapy

-OR-

(2) Diagnosis of **one** of the following:

(a) Primary cutaneous marginal zone lymphoma
(b) Follicle center refractory generalized cutaneous B-cell lymphoma
(c) Refractory generalized T3 cutaneous B-cell lymphoma

Authorization will be issued for 12 months.

2. Reauthorization

a. Zydelig will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zydelig therapy

Authorization will be issued for 12 months.

3. References:

1. Zydelig [package insert]. Foster City, CA: Gilead Science, Inc. September 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 19, 2017.

Program	Prior Authorization - Zydelig (idelalisib)
Change Control	
Date	Change
10/2014	New program
9/2016	Updated clinical criteria to align with E&I notification policy and updated policy template.
9/2017	Annual Review. Added coverage for additional nodal marginal zone lymphoma. Updated background and references.