UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zydelig

Program	Prior Authorization
Medication	Zydelig® (idelalisib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	10/2014
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Zydelig (idelalisib) is a phosphatidylinositol 3-kinase inhibitor 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, splenic marginal zone lymphoma, and nodal marginal zone lymphoma.[2]

Zydelig has a black box warning for colitis, diarrhea, intestinal perforation, hepatotoxicity, infection and pneumonitis. Please see full prescribing information for additional details.

2. Coverage Criteria:

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

1. <u>Initial Authorization</u>

a. Zydelig will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of **<u>one</u>** 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) Diagnosis of **one** of the following:

i. Follicular lymphoma (FL)
ii. Gastric MALT Lymphoma
iii. Nongastric MALT Lymphoma
iv. Marginal Zone Lymphoma

-AND-

(b) Patient has failed two prior therapies

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.

UnitedHealthcare Community Plan

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Zydelig** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Zydelig therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Zydelig [package insert]. Foster City, CA: Gilead Science, Inc.October 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August4, 2020.

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.
9/2018	Annual review. Added NCCN Recommended regimen review criteria. Updated references.
9/2019	Updated NHL section based on NCCN guidelines. Updated references.

9/2020	Annual review. No changes to coverage criteria. Updated background references. Added Additional Clinical rules section.