UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1145-12
Program	Prior Authorization/Notification
Medication	Zydelig® (idelalisib)
P&T Approval Date	10/2014, 10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 5/2022, 5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Zydelig (idelalisib) is a kinase inhibitor indicated for the treatment of patients with 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.[1,2] The National Cancer Comprehensive Network (NCCN) also recommends the use of Zydelig as second-line and subsequent therapy as a single agent or in combination with rituximab for CLL/SLL with del(17p)/TP53 mutation in patients who have indications for treatment.[2]

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

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

1. **<u>Initial Authorization</u>**

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

      (1) Diagnosis of Chronic Lymphocytic Leukemia (CLL) / small lymphocytic lymphoma (SLL)

      -AND-

      (2) **<u>One</u>** 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.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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. February 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 27, 2025.

Program	Prior Authorization/Notification - Zydelig (idelalisib)
Change Control	
10/2014	New program for Zydelig approved by FDA on 6/23/2014.
10/2015	Annual review. Added coverage for gastric and nongastric MALT lymphomas, and splenic marginal zone lymphoma. Revised CLL/SLL and primary cutaneous B-cell lymphoma criteria. Updated background and references.
9/2016	Annual review. Added coverage for additional cutaneous B-cell lymphoma diseases. Updated references.

9/2017	Annual review. Added coverage for additional nodal marginal zone lymphoma. Updated background and references.
9/2018	Annual review. No changes to the coverage criteria. Updated references.
9/2019	Annual review. Updated NHL section based on NCCN guidelines. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review. No changes to coverage criteria. Updated background references.
10/2021	Annual review. Reclassified Non-Hodgkin Lymphoma to B-cell Lymphomas to align with NCCN guidelines. Updated references.
5/2022	Annual review. Removed coverage for follicular B-cell non-Hodgkin lymphoma, small lymphocytic lymphoma, gastric and nongastric MALT lymphomas, splenic marginal zone lymphoma, and nodal marginal zone lymphoma based on package insert and NCCN guidelines. Updated background and references.
5/2023	Annual review. Added state mandate. Updated background and clarified criteria for CLL/SLL per NCCN guidelines. Updated references.
5/2024	Annual review. Updated references.
5/2025	Annual review. No changes to clinical criteria. Updated references.