VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Zydelig Prior Authorization Policy
- Zydelig® (idelalisib tablets – Gilead)

REVIEW DATE: 06/23/2021

OVERVIEW

Zydelig, a phosphatidylinositol 3-kinase inhibitor, is indicated for the following uses:[1]

- **Chronic lymphocytic leukemia (CLL)**, relapsed, in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other comorbidities.

Limitations of use: Zydelig is not indicated and is not recommended for first-line treatment of any patient, including patients with CLL, small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and other indolent non-Hodgkin lymphomas. Zydelig is not indicated and is not recommended in combination with bendamustine and rituximab, or in combination with rituximab for the treatment of patients with FL, SLL, and other indolent non-Hodgkin lymphomas.

Guidelines

Zydelig is discussed in guidelines from The National Comprehensive Cancer Network (NCCN):

- **B-Cell Lymphomas:** The NCCN guidelines (version 4.2021 – May 5, 2021) address follicular lymphoma and marginal zone lymphoma.[2] The guidelines recommend Zydelig as third-line and subsequent therapy for relapsed/refractory or progressive follicular lymphoma (grade 1-2) after two prior therapies. The guidelines recommend Zydelig as second-line and subsequent therapy for marginal zone lymphomas that are relapsed/refractory to two prior therapies.
- **CLL/SLL:** The NCCN guidelines (version 2.2022 – January 18, 2022) recommend Zydelig with or without rituximab as second-line and subsequent therapy with or without del(17p)/TP53 mutations (category 2A).[3] Many other agents have a more prominent role in the first-line management of CLL. The guidelines note that CLL and SLL are different manifestations of the same condition and are treated similarly.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Zydelig. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Zydelig is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Chronic Lymphocytic Leukemia.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least two systemic regimens.
   Note: Examples of systemic regimens contain one or more of the following products: Imbruvica (ibrutinib capsules and tablets), Venclexta (venetoclax tablets), chlorambucil, Gazyva (obinutuzumab injection for intravenous use), rituximab, fludarabine, cyclophosphamide, pentostatin, Treanda (bendamustine injection), Campath (alemtuzumab injection for intravenous use), Calquence (acalabrutinib capsules), Arzerra (ofatumumab injection for intravenous use), or Copiktra (duvelisib capsules).

Other Uses with Supportive Evidence

2. **Follicular Lymphoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least two systemic regimens.
   Note: Examples of systemic regimens contain one or more of the following products: Treanda (bendamustine injection), rituximab, Gazyva (obinutuzumab injection for intravenous use), cyclophosphamide, doxorubicin, vincristine, prednisone, chlorambucil, or Revlimid (lenalidomide capsules).

3. **Marginal Zone Lymphoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   Note: Marginal Zone Lymphoma includes Gastric MALT Lymphoma, Nongastric MALT Lymphoma, Nodal Marginal Zone Lymphoma, and Splenic Marginal Zone Lymphoma.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least two other systemic regimens.
   Note: Examples of systemic regimens contain one or more of the following products: rituximab, Treanda (bendamustine injection for intravenous use), cyclophosphamide, vincristine, prednisone, chlorambucil, Imbruvica (ibrutinib tablets and capsules), Copiktra (duvelisib capsules), Revlimid (lenalidomide capsules), or Aliqopa (copanlisib injection for intravenous use).

4. **Small Lymphocytic Lymphoma.** Approve for 3 years if the patient meets the following criteria: (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least two systemic regimens.
   Note: Examples of systemic regimens contain one or more of the following products: Imbruvica (ibrutinib capsules or tablets), Venclexta (venetoclax tablets), chlorambucil, Gazyva (obinutuzumab injection for intravenous use), rituximab, fludarabine, cyclophosphamide, pentostatin, Treanda (bendamustine injection), Calquence (acalabrutinib capsules), Arzerra (ofatumumab injection for intravenous use), or Copiktra (duvelisib capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zydelig is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zydelig® tablets [prescribing information]. Foster City, CA: Gilead Sciences; February 2022.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2021 – May 5, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 9, 2021
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 2.2022 – January 18, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**The following changes were made:** 1. **Chronic Lymphocytic Leukemia:** The wording of "at least" was added to the requirement that patients try two therapies. Also, the examples of therapies were removed from the criteria and placed into a note. Chlorambucil plus Arzerra® (ofatumumab injection for intravenous use) was removed from the list of examples. 2. **Follicular Lymphoma:** The wording of "at least" was added to the requirement that patients try two therapies. Also, the examples of therapies were removed from the criteria and placed into a note. 3. **Small Lymphocytic Lymphoma:** The wording of "at least" was added to the requirement that patients try two therapies. Also, the examples of therapies were removed from the criteria and placed into a note. Chlorambucil plus Arzerra® (ofatumumab injection for intravenous use) was removed from the list of examples. 4. **Marginal Zone Lymphoma:** The wording of "at least" was added to the requirement that patients try two therapies. Also, the examples of therapies were removed from the criteria and placed into a note.	06/03/2020
Annual Revision	**Chronic Lymphocytic Leukemia (CLL):** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient has tried two prior therapies was reworded to the patient has tried two systemic regimens. **Follicular Lymphoma:** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient has tried two prior therapies was reworded to the patient has tried two systemic regimens. **Small Lymphocytic Lymphoma (SLL):** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient has tried two prior therapies was reworded to the patient has tried two systemic regimens. **Marginal Zone Lymphoma:** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient has tried two prior therapies was reworded to the patient has tried two systemic regimens. A Note was added with the types of Marginal Zone Lymphoma.	06/23/2021
Update	**02/23/2022:** **Follicular Lymphoma:** Condition of approval and criteria were moved from FDA-approved indications into Other Uses with Supportive Evidence due to change in FDA-labeling. **Small Lymphocytic Lymphoma:** Condition of approval and criteria were moved from FDA-approved indications into Other Uses with Supportive Evidence due to change in FDA-labeling.	N/A