PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/22/2022

OVERVIEW

Zydelig, a phosphatidylinositol 3-kinase (PI3K) inhibitor, is indicated for relapsed **chronic lymphocytic leukemia (CLL)** in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other comorbidities.[1]

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.[1]

Guidelines

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

- **B-Cell Lymphomas:** NCCN guidelines (version 4.2022 – June 9, 2022) address follicular lymphoma and marginal zone lymphoma.[2] The guidelines previously recommended Zydelig as third-line and subsequent therapy for relapsed/refractory or progressive follicular lymphoma (grade 1-2) after two prior therapies, but no longer recommend Zydelig for this scenario. The guidelines previously recommended Zydelig as second-line and subsequent therapy for marginal zone lymphomas that are relapsed/refractory to two prior therapies, but no longer recommend Zydelig for this scenario.
- **CLL/SLL:** NCCN guidelines (version 3.2022 – June 3, 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 one of the following criteria:

FDA-Approved Indication

1. **Chronic Lymphocytic Leukemia.** Approve for 1 year 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. **Marginal Zone Lymphoma.** Approve for 1 year if the patient meets the following criteria (A, B and C):
   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)** The patient is currently receiving Zydelig AND
   - **C)** 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).

3. **Small Lymphocytic Lymphoma.** Approve for 1 year 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 4.2022 – June 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 13, 2022
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2022 – June 3, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 13, 2022.