PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/12/2024

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). NCCN **CLL/SLL** guidelines (version 3.2024 – March 26, 2024) recommend Zydelig with or without rituximab as "other recommended regimens" for relapsed or refractory disease after prior Bruton tyrosine kinase inhibitor and venetoclax-based regimens for patients with or without del(17p)/TP53 mutations.[2] 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:

FDA-Approved Indication

1. **Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least one Bruton tyrosine kinase inhibitor; AND
     Note: Examples of a Bruton tyrosine kinase inhibitor includes: Imbruvica (ibrutinib capsules, tablets, and oral solution); Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), or Jaypirca (pirtobrutinib tablets).
   - **C)** Patient has tried at least one Venclexta-based regimen.

Other Uses with Supportive Evidence

2. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one Bruton tyrosine kinase inhibitor; AND
   Note: Examples of a Bruton tyrosine kinase inhibitor includes: Imbruvica (ibrutinib capsules, tablets, and oral solution); Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), or Jaypirca (pirtobrutinib tablets).
   C) Patient has tried at least one Venclexta-based regimen.

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 Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2024 – March 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 6, 2024.