PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/28/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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):

- **CLL/SLL:** NCCN guidelines (version 3.2023 – June 12, 2023) 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 without del(17p)/TP53 mutations and as second-line or third-line therapy for patients with del(17p)TP53 mutation (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.

- **Zydelig® (idelalisib tablets (Gilead)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least one systemic regimen.
     Note: Examples of systemic regimens contain one or more of the following products: Imbruvica (ibrutinib capsules, tablets, and oral solution), Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), Venclexta (venetoclax tablets), chlorambucil, Gazyva (obinutuzumab intravenous infusion), rituximab, fludarabine, cyclophosphamide, bendamustine, high-dose methylprednisolone, Campath (alemtuzumab intravenous infusion), or Arzerra (ofatumumab intravenous infusion).

Other Uses with Supportive Evidence

2. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least one systemic regimen.
     Note: Examples of systemic regimens contain one or more of the following products: Imbruvica (ibrutinib capsules, tablets, or oral solution), Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), Venclexta (venetoclax tablets), chlorambucil, Gazyva (obinutuzumab intravenous infusion), rituximab, fludarabine, cyclophosphamide, bendamustine, high-dose methylprednisolone, Campath (alemtuzumab intravenous infusion), or Arzerra (ofatumumab intravenous infusion).

CONDITIONS NOT COVERED

- **Zydelig® (idelalisib tablets (Gilead)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

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 3.2023 – June 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Chronic Lymphocytic Leukemia:** The duration of approval was changed from 3 years to 1 year. **Follicular Lymphoma:** Condition of approval and criteria was removed from the policy based on NCCN guideline changes. **Marginal Zone Lymphoma:** The duration of approval was changed from 3 years to 1 year. A requirement that the patient is continuing therapy with Zydelig was added. **Small Lymphocytic Lymphoma:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	**Chronic Lymphocytic Leukemia:** The requirement that the patient has tried at least two systemic regimens was changed to one systemic regimen. **Marginal Zone Lymphoma:** Condition of approval and criteria was removed from the policy based on NCCN guideline changes. **Small Lymphocytic Lymphoma:** The requirement that the patient has tried at least two systemic regimens was changed to one systemic regimen.	06/28/2023