

Clinical Policy: Idelalisib (Zydelig)

Reference Number: HIM.PA.SP49

Effective Date: 12.01.17

Last Review Date:

Line of Business: Health Insurance Marketplace

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Idelalisib (Zydelig[®]) is a kinase inhibitor.

FDA Approved Indication(s)

Zydelig is indicated for the treatment of:

- 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
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies*
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies*

**Accelerated approval was granted for FL and SLL based on overall response rate. Improvement in patient survival or disease related symptoms has not been established. Continued approval for these indications may be contingent upon verification of clinical benefit in confirmatory trials.*

Limitation(s) of use: Zydelig is not indicated and is not recommended for first-line treatment of any patient.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Chronic Lymphocytic Leukemia (must meet all):

1. Diagnosis of CLL;
2. Disease is relapsed or refractory to first-line therapy (e.g., obinutuzumab, ibrutinib, ofatumumab, rituximab, fludarabine, alemtuzumab, alkylator therapy [e.g., bendamustine, chlorambucil, cyclophosphamide]);
3. Meets a or b:
 - a. FDA approved use: Zydelig will be used in combination with rituximab;
 - b. Off-label NCCN recommended use: Zydelig will be used as a single agent;
4. Request meets one of the following (a or b):
 - a. Dose does not exceed 300 mg/day (2 tablets/day);
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Follicular B-Cell Non-Hodgkin Lymphoma (must meet all):

1. Diagnosis of FL;
2. Disease is relapsed or refractory to first-line therapy (e.g., rituximab, obinutuzumab, doxorubicin, vincristine, alkylator therapy [e.g., bendamustine, chlorambucil, cyclophosphamide]);
3. Member has received at least 2 prior systemic therapies (e.g., any of the first-line therapies listed above, lenalidomide);
4. Dose does not exceed 300 mg/day (2 tablets/day).

Approval duration: 6 months

C. Small Lymphocytic Lymphoma (must meet all):

1. Diagnosis of SLL;
2. Disease is relapsed or refractory to first-line therapy (e.g., obinutuzumab, ibrutinib, ofatumumab, rituximab, fludarabine, alemtuzumab, alkylator therapy [e.g., bendamustine, chlorambucil, cyclophosphamide]);
3. Meets a or b:
 - a. FDA approved use (i and ii):
 - i. Member has received at least 2 prior systemic therapies (e.g., any of the first-line therapies listed above, venetoclax);
 - ii. Zydelig will be used as a single agent;
 - b. Off-label NCCN recommended use:
 - i. Zydelig will be used in combination with rituximab;
4. Request meets one of the following (a or b):
 - a. Dose does not exceed 300 mg/day (2 tablets/day);
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Other Non-Hodgkin Lymphomas (off-label) (must meet all):

1. Diagnosis of one of the following non-Hodgkin lymphomas (a, b, or c):
 - a. Mucosa-associated lymphoid tissue (MALT) lymphoma (gastric or nongastric);
 - b. Marginal zone lymphoma (nodal or splenic);
 - c. Primary cutaneous B-cell lymphoma (marginal zone or follicle center);
2. Member meets one of the following (a or b):
 - a. For any diagnosis: Disease is refractory to both alkylator (e.g., bendamustine, chlorambucil, cyclophosphamide) and rituximab therapy, and Zydelig is being used as a second-line or subsequent therapy;
 - b. For primary cutaneous B-cell lymphoma only: Member has very extensive or refractory generalized T3 (multiple lesions involving 2 noncontiguous body regions or involving ≥ 3 body regions) cutaneous disease;
3. Request meets one of the following (a or b):
 - a. Dose does not exceed 300 mg/day (2 tablets/day);

- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 300 mg/day (2 tablets/day);
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CLL: chronic lymphocytic leukemia

FDA: Food and Drug Administration

FL: follicular B-cell non-Hodgkin lymphoma

NCCN: National Comprehensive Cancer Network

SLL: small lymphocytic lymphoma

V. References

1. Zydelig Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; September 2016. Available at <http://www.zydelig.com>. Accessed August 29, 2017.
2. Idelalisib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed August 29, 2017.

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3. Chronic lymphocytic leukemia/small lymphocytic lymphoma (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed August 29, 2017.
4. B-cell lymphomas (Version 3.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed August 29, 2017.
5. Primary cutaneous B-cell lymphomas (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed August 29, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.29.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

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recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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