Prior Authorization Approval Criteria

Zydelig (Idelalisib)

Generic name: Idelalisib
Brand name: Zydelig
Medication class: Kinase inhibitor; antineoplastic
FDA-approved uses: Treatment of patients with:
- 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 therapies.
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Prescribed by an oncologist or hematologist
- Patient must be 18 years of age or older
- Idelalisib is not being used as first line treatment
- Clinically diagnosed with relapsed chronic lymphocytic leukemia (CLL) and is being used in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
  OR
- Clinically diagnosed relapsed follicular B-cell non-Hodgkin lymphoma (FL) and must have failure/intolerance or contraindication to at least two prior therapies
  OR
- Clinically diagnosed relapsed small lymphocytic lymphoma (SLL) and must have failure/intolerance or contraindication to at least two prior systemic therapies
- Must not have a history of serious allergic reactions including anaphylaxis or toxic epidermal necrolysis.

Criteria for continuation of therapy:
- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

Caution:
- Fatal and/or serious hepatotoxicity occurred in 14% of patients
- Fatal and/or serious and severe diarrhea or colitis occurred in 14% of patients
- Fatal and/or serious pneumonitis can occur
- Fatal and/or serious intestinal perforation can occur
- Severe cutaneous reactions
- Anaphylaxis
- Neutropenia

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
- Embryo-fetal toxicity

Approval Duration:
- Initial 6 months
- Renewal 1 year

Benefit Type:
- Pharmacy

** Off-label Use:
Fallon may authorize coverage of the requested medication for use in other cancer diagnoses with submitted documentation that the drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

If the requested off-label use is not acknowledged by the NCCN Drugs and Biologics Compendium, Fallon will abide by the Centers for Medicare and Medicaid Services (CMS) guidance or Massachusetts regulations¹ accepting documentation of recommended off-label use of the requested medication in any one of the following:

1. One of the following standard reference compendia:
   - American Hospital Formulary Service – Drug information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - Wolters Kluwer Lexi-Drugs

2. Peer-reviewed published medical literature indicating that sufficient evidence exists to support use.

¹Reference: [https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K](https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K) accessed 7/7/2017

Adopted: 09/17/14
Reviewed: 9/13/17- updated criteria for use, approval duration & continuation of therapy, removed contraindications, not approved if and special considerations, added benefit type

Reviewed: 11/28/17 – for peer reviewed literature, replaced “determined by Fallon” with “indicating”