ALASKA MEDICAID
Prior Authorization Criteria

Zydelig® (idelalisib)

Black Box Warning

- Refer to package insert for specific warning information on serious and/or fatal hepatotoxicity, colitis, pneumonitis, and intestinal perforation risks while taking idelalisib.

FDA INDICATIONS AND USAGE

- Relapsed chronic lymphocytic leukemia (CLL) in combination with rituximab.
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small lymphocytic lymphoma (SLL) in patients who have trialed at least two prior systemic therapies.

APPROVAL CRITERIA

1. Patients with a diagnosis of relapsed chronic lymphocytic leukemia (CLL) taken in combination with rituximab; **OR**
2. Patients with a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) who have trialed at least two prior systemic therapies; **OR**
3. Patients with a diagnosis of relapsed small lymphocytic lymphoma (SLL) who have trialed at least two prior systemic therapies.

DENIAL CRITERIA:

1. Renewal authorizations will not be approved if the patient has had AST/ALT > 20 time the upper limit of normal (ULN), Bilirubin > 10 times the ULN, or life-threatening diarrhea.
2. Pregnancy

CAUTIONS:

- Zydelig should only be used in the treatment of relapsed CLL in patients for whom rituximab alone would be considered appropriate when taking into account the patient's other co-morbidities.
- Zydelig approval for FL and SLL was based on Overall Response Rate; improvements in patient survival or disease symptoms have not been established.

DURATION OF APPROVAL:

- Approval may be granted up to 1 year

QUANTITY LIMIT:

- Two 150mg capsules per day

REFERENCES / FOOTNOTES:

1. Zydelig® [package insert]. Foster City, CA; Gilead Sciences, Inc., July 2014.