IDELALISIB

Generic	Brand	HICL	GCN	Exception/Other
IDELALISIB	ZYDELIG	41297		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed chronic lymphocytic leukemia (CLL)?

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient on chemotherapy in combination with rituximab?

   If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) and has received two prior systemic therapies?

   If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of relapsed small lymphocytic lymphoma (SLL) and has received at least two prior systemic therapies?

   If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **IDELALISIB** requires a diagnosis of relapsed chronic lymphocytic leukemia (CLL) with concomitant treatment with rituximab, relapsed follicular B-cell non-Hodgkin lymphoma (FL) or relapsed small lymphocytic lymphoma (SLL) and having received two prior systemic therapies.

CONTINUED ON NEXT PAGE

IDELALISIB

GUIDELINES FOR USE (CONTINUED)

Table 1. Chronic Lymphocytic Leukemia (CLL) Treatment Options (please refer to NCCN for most current guideline)

chlorambucil
ibrutinib
Obinutuzumab+chlorambucil
Idelalisib+rituximab
Bendamustine+/-rituximab
ofatumumab
fludarabine
cladribine
rituximab
alemtuzumab IV
alemtuzumab (Campath) SC+/-rituximab
chlorambucil + prednisone
fludarabine+prednisone
fludarabine+cyclophosphamide (FC)
Fludarabine+alemtuzumab
Rituximab+chlorambucil
fludarabine+rituximab
fludarabine+cyclophosphamide rituximab (FCR)
cladribine+mitoxantrone+cyclophosphamide (CMC)
cyclophosphamide+vincristine+prednisone (CVP)
lenalidomide+/-rituximab
pentostatin+cyclophosphamide+rituximab (PCR)
cyclophosphamide+fludarabine+alemtuzumab+rituximab (CFAR)
rituximab+cyclophosphamide+doxorubicin+vincristine+prednisone (RCHOP)
Oxaliplatin+fludarabine+cytarabine+rituximab (OFAR)

RATIONALE
Promote appropriate utilization and dosing of idelalisib based or their FDA approved indication.

DOSAGE
The recommended maximum starting dose of Zydelig is 150 mg administered orally twice daily.

Dose modification may be required for specific toxicities related to Zydelig. If resuming Zydelig after interruption for other severe or life-threatening toxicities, reduce the dose to 100 mg twice daily.

CONTINUED ON NEXT PAGE

IDELALISIB

FDA APPROVED INDICATIONS

Zydelig is a kinase inhibitor indicated for the 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 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.

REFERENCES

- Gilead Sciences, Inc. Zydelig package insert. Foster City, CA. July 2014
- NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 4.2014. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf [Accessed October 15, 2014]

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/15
Created: 08/14
Client Approval: 11/14
P&T Approval: 11/14