VEMURAFENIB

Generic	Brand	HICL	GCN	Exception/Other
VEMURAFENIB	ZELBORAF	37837		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet the following criterion?
   - The patient has a genetic mutation called BRAF V600E as detected by an FDA-approved test

     If yes, **approve for 12 months with a quantity limit of #8 tablets per day.**
     If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester Disease and meet the following criterion?
   - The patient has a genetic mutation called BRAF V600

     If yes, **approve for 12 months with a quantity limit of #8 tablets per day.**
     If no, do not approve.
     DENIAL TEXT: The guideline named **VEMURAFENIB (Zelboraf)** requires a diagnosis of unresectable or metastatic melanoma with a BRAF V600E mutation as detected by an FDA-approved test or Erdheim-Chester Disease with a BRAF V600 mutation.

RATIONALE
Ensure appropriate use of vemurafenib based on FDA approved indication.

FDA APPROVED INDICATIONS
Zelboraf is a kinase inhibitor indicated for:
- Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test
- Treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation

Limitation of Use: Zelboraf is not recommended for use in patients with wild-type BRAF melanoma.

DOSAGE AND ADMINISTRATION
Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with ZELBORAF.

Recommended dose: 960 mg orally twice daily taken approximately 12 hours apart with or without a meal.

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REFERENCES

- Genentech, Inc. Zelboraf package insert. South San Francisco, CA. November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/17
Created: 08/11
Client Approval: 11/17
P&T Approval: 01/18