ENCORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
ENCORAFENIB	BRAFTOVI	45039		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The medication will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL with a quantity limit of #6 capsules per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **ENCORAFENIB (Braftovi)** requires a diagnosis of unresectable or metastatic melanoma. In addition, the following criteria must be met:
   - The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The medication will be used in combination with Mektovi (binimetinib)

RATIONALE
To promote appropriate utilization of BRAFTOVI based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS
Braftovi is a kinase inhibitor indicated, in combination with Mektovi (binimetinib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

Limitations of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma.

DOSAGE & ADMINISTRATION
The recommended dosage of Braftovi is 450 mg orally taken once daily in combination with Mektovi (binimetinib) until disease progression or unacceptable toxicity. Refer to the Mektovi (binimetinib) prescribing information for recommended Mektovi (binimetinib) dosing information.

Braftovi may be taken with or without food. Do not take a missed dose of Braftovi within 12 hours of the next dose of Braftovi. Do not take an additional dose if vomiting occurs after Braftovi administration but continue with the next scheduled dose.

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REFERENCES

- Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/18
Created: 08/18
Client Approval: 07/18
P&T Approval: 07/18