

Commercial/Healthcare Exchange Prior Authorization Criteria

Effective: November 7th, 2018

Prior Authorization: Braftovi

Products Affected: Braftovi (encorafenib) oral capsules

Medication Description:

Braftovi (encorafenib) is a kinase inhibitor that targets BRAF V600E, as well as wild-type BRAF and CRAF in in vitro cell-free assays. It was also able to bind to other kinases in vitro including JNK1, JNK2, JNK3, LIMK1, LIMK2, MEK4, and STK36. It inhibited in vitro growth of tumor cell lines expressing BRAF V600E, D, and K mutations.

Braftovi is indicated, in combination with 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.

Covered Uses:

1. Malignant melanoma, unresectable or metastatic, with a BRAF V600E or V600K mutation, in combination with binimetinib
2. BRAF V600E Mutation-Positive Metastatic Colorectal Cancer (CRC) in combination with cetuximab

Exclusion Criteria:

1. Wild-type BRAF melanoma
2. Wild-type BRAF CRC

Required Medical Information:

1. Diagnosis
2. BRAF mutation status
3. Previous therapies tried

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 3 years

Other Criteria:

Braftovi (encorafenib) will be approved for the following diagnosis when the subsequent criteria are met:

Malignant Melanoma

- A. Patient has a diagnosis of malignant melanoma; **AND**
- B. Patient's disease is unresectable or metastatic; **AND**
- C. Presence of BRAF V600E or V600K mutation has been confirmed by an FDA approved test; **AND**
- D. Braftovi (encorafenib) will be used in combination with Mektovi (binimetinib)

Metastatic Colorectal Cancer

- a. Patient has a diagnosis of metastatic colorectal cancer; **AND**
- b. Patient has BRAF V600E mutation-positive disease, as confirmed by an FDA approved test; **AND**
- c. Patient has tried and failed at least 1 prior therapy; **AND**
- d. Braftovi will be used in combination with cetuximab

References:

- 1. Braftovi [package insert]. Boulder, CO; Array BioPharma; June 2018

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	09/14/18
2	Policy Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019
3	Update	Added indication for BRAF V600E Mutation-Positive Metastatic Colorectal Cancer (CRC) to medication description and covered uses Added wild-type BRAF CRC to exclusions Other criteria added to new indication, metastatic colorectal cancer	Medication description Covered uses Exclusion criteria Other criteria	6/2/2020