UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Braftovi

Program	Prior Authorization
Medication	Braftovi (encorafenib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2018
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Braftovi™ (encorafenib) 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. Braftovi is also indicated in combination with Erbitux (cetuximab), for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation after prior therapy.

The National Cancer Comprehensive Network (NCCN) guideline recommends use of Braftovi in combination with Erbitux or Vectibix (panitumumab) in previously treated patients with metastatic or advanced colorectal cancer with a BRAF V600E mutation.

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

Information on FDA-approved tests for the detection of BRAF V600 mutations in melanoma may be found at: http://www.fda.gov/CompanionDiagnostics.[1]

2. Coverage Criteria:

A. <u>Melanoma</u>

1. **<u>Initial Authorization</u>**

   a. **Braftovi** will be approved based on **<u>all</u>** of the following criteria:

      (1) **<u>One</u>** of the following diagnoses:

(a) Unresectable melanoma

(b) Metastatic melanoma

-AND-

(2) Patient is positive for BRAFV600 mutation

-AND-

(3) Used in combination with Mektovi (binimetinib)

-AND-

(4) **One** of the following:

(a) Patient has a contraindication or history of intolerance to **one** of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

-OR-

(b) Provider attests that the patient is not an appropriate candidate for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

-OR-

(c) For continuation of prior Braftovi therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Braftovi** will be approved based on **both** of the following criteria:

(1) Patient does not show evidence of progressive disease while on Braftovi therapy

-AND-

(2) Used in combination with Mektovi (binimetinib)

Authorization will be issued for 12 months.

B. Colon Cancer

1. Initial Authorization

a. **Braftovi** will be approved based on **all** of the following:

(1) Diagnosis of colon cancer

-AND-

(2) Cancer is positive for BRAF V600E mutation

-AND-

(3) **One** of the following:

(a) Unresectable or advanced disease
(b) Metastatic disease

-AND-

(4) Patient has received prior therapy

-AND-

(5) Used in combination with **one** of the following:

(a) Erbitux (cetuximab)
(b) Vectibix (panitumumab)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Braftovi** will be approved based on the following criterion.:

(1) Patient does not show evidence of progressive disease while on Braftovi

therapy

Authorization will be issued for 12 months.

C. Rectal Cancer

1. Initial Authorization

a. **Braftovi** will be approved based on **all** of the following:

(1) Diagnosis of rectal cancer

-AND-

(2) Cancer is positive for BRAF V600E mutation

-AND-

(3) **One** of the following:

(a) Unresectable or advanced disease
(b) Metastatic disease

-AND-

(4) Patient has received prior therapy

-AND-

(5) Used in combination with **one** of the following:

(a) Erbitux (cetuximab)
(b) Vectibix (panitumumab)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Braftovi** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Braftovi therapy

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Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Braftovi** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Braftovi** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Braftovi therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Braftovi [package insert]. Boulder, CO: Array BioPharma Inc.; April 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 12, 2020.

Program	Prior Authorization –Braftovi (encorafenib)
Change Control	
Date	Change
8/2018	New Program
1/2019	Added trial of alternative regimen prior to coverage for Braftovi/Mektovi. Updated references.
9/2019	Updated background and criteria to include NCCN recommended use in BRAF V600E colorectal cancer. Updated references.
6/2020	Updated background and criteria to include new indication of BRAF V600E mutated colorectal cancer. Removed specific drug list for prior therapy requirement. Modified criteria for BRAF V600E mutated colorectal cancer to also include NCCN

	recommended use which no longer requires concomitant Mektovi. Updated References. Added Additional Clinical Rules section.