UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1255-7
Program	Prior Authorization/Notification
Medication	Braftovi® (encorafenib)
P&T Approval Date	8/2018, 9/2019, 6/2020, 6/2021, 6/2022, 6/2023, 12/2023
Effective Date	3/1/2024

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, in combination with Mektovi, is also indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation. Braftovi. in combination with Erbitux® (cetuximab), is indicated 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.

Limitations of Use

Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC.

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

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Melanoma

1. **Initial Authorization**

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

(1) **One** of the following diagnoses:

(a) Unresectable melanoma

(b) Metastatic melanoma

-AND-

(2) Patient is positive for BRAF V600E mutation

-AND-

(3) Used in combination with Mektovi (binimetinib)

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.

C. 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 **both** of the following criteria:

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

-AND-

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

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

Authorization will be issued for 12 months.

D. 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 **both** of the following criteria:

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

-AND-

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

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

Authorization will be issued for 12 months.

E. Non-Small Cell Lung Cancer

1. **Initial Authorization**

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

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is metastatic

-AND-

(3) Patient is positive for BRAFV600 mutation

-AND-

(4) Used in combination with Mektovi (binimetinib)

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.

F. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.; October 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 16, 2023.

Program	Prior Authorization/Notification - Braftovi (encorafenib)
Change Control	
8/2018	New program
9/2019	Annual review. Updated background and criteria to include NCCN recommended use in BRAF V600 E colorectal cancer. Updated references. Added general NCCN recommended review criteria.
6/2020	Updated background and criteria to include new indication of BRAF V600E mutated colorectal cancer. Modified criteria for BRAF V600E mutated colorectal cancer to also include NCCN recommended use which no longer requires concomitant Mektovi.
6/2021	Annual review with no change to criteria. Updated reference.
6/2022	Annual review. Added continuation of combination therapy to colon and rectal cancer. Updated background and references.
6/2023	Annual review with no change to criteria. Added state mandate footnote. Updated reference.
12/2023	Updated background and criteria to include new FDA approved use in BRAF V600E NSCLC. Updated references.