UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1255-10
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, 6/2024, 2/2025, 6/2025
Effective Date	9/1/2025

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 Erbitux® (cetuximab) and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin), is indicated for the treatment of patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation. Braftovi, in combination with Erbitux® (cetuximab), is indicated for the treatment of patients with metastatic CRC with a BRAF V600E mutation after prior therapy. The National Cancer Comprehensive Network (NCCN) Compendium recommends the use of Braftovi, in combination with Erbitux or Vectibix (panitumumab), in patients with metastatic or advanced colorectal cancer with a BRAF V600E 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. The NCCN Compendium also recommends the use of Braftovi, in combination with Mektovi for the treatment of recurrent and advanced NSCLC with BRAF V600E mutation.
Limitations of Use
Braftovi is not indicated for the treatment of patients with wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC.

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.

© 2025 UnitedHealthcare Services, Inc.

B. Melanoma

1. **Initial Authorization**

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

(1) Diagnosis of melanoma

-AND-

(2) Presence of BRAF V600E mutation

-AND-

(3) Disease is **one** of the following:

(a) Unresectable
(b) Metastatic

-AND-

(4) 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/Rectal Cancer

1. **Initial Authorization**

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

(1) Diagnosis of colon or rectal cancer

-AND-

(2) Presence of BRAF V600E mutation

© 2025 UnitedHealthcare Services, Inc.

-AND-

(3) Disease is **one** of the following:

(a) Advanced
(b) Metastatic

-AND-

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

(a) **Both** of the following:

i. Patient has received prior therapy with an oxaliplatin-based regimen (e.g., FOLFOX, CAPEOX)

-AND-

ii. Used in combination with Erbitux (cetuximab) or Vectibix (panitumumab)

-OR-

(b) **Both** of the following:

i. Patient has not received prior therapy with an oxaliplatin-based regimen (e.g., FOLFOX, CAPEOX)

-AND-

ii. Used in combination with **both** of the following:

- Erbitux (cetuximab) or Vectibix (panitumumab)

-AND-

- FOLFOX (fluorouracil, leucovorin, and oxaliplatin)

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)

© 2025 UnitedHealthcare Services, Inc.

(b) Vectibix (panitumumab)
(c) Erbitux (cetuximab) and FOLFOX (fluorouracil, leucovorin, and oxaliplatin)
(d) Vectibix (panitumumab) and FOLFOX

Authorization will be issued for 12 months.

D. 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) Presence of BRAFV600 mutation

-AND-

(3) Disease is **one** of the following:

(a) Advanced
(b) Recurrent
(c) Metastatic

-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

-AND-

(2) Used in combination with Mektovi (binimetinib)

Authorization will be issued for 12 months.

E. 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

© 2025 UnitedHealthcare Services, Inc.

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.; December 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium®). Available at www.nccn.org. Accessed April 30, 2025.

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.
6/2024	Annual review. Updated language and formatting of criteria for melanoma, colon cancer, and rectal cancer with no change in intent. Added coverage for advanced and recurrent NSCLC per NCCN Compendium. Added reauthorization requirement for NSCLC that Braftovi is used in combination with Mektovi. Updated references.
2/2025	Updated background and criteria to include new FDA approved use in combination with Erbitux and mFOLFOX6 in BRAF V600E mutated colorectal cancer.

© 2025 UnitedHealthcare Services, Inc.

6/2025	Annual review. Combined criteria sections for colon and rectal cancer. Updated initial and reauthorization criteria for colon and rectal cancer. Updated background and references.

© 2025 UnitedHealthcare Services, Inc.