Generic Name: encorafenib

Therapeutic Class or Brand Name: BRAF Inhibitor

Applicable Drugs (if Therapeutic Class): Braftovi (encorafenib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/9/2019

Date Last Reviewed: 6/11/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indication(s)

A. Unresectable or metastatic melanoma
   1. Documentation of BRAF V600E or V600K mutations.
   2. Used in combination with Mektovi (binimetinib).

B. Metastatic colorectal cancer
   1. Documentation of BRAF V600E mutation AND either a or b
      a) Used in combination with Erbitux (cetuximab) and fluorouracil-based chemotherapy.
      b) Used in combination with Erbitux (cetuximab) after prior therapy.

C. Metastatic non-small cell lung cancer (NSCLC)
   1. Documentation of BRAF V600E mutation.
   2. Used in combination with Mektovi (binimetinib).

Other Uses With Supportive Evidence

A. BRAF V600 mutation positive cutaneous melanoma.

B. BRAF V600E mutation positive rectal cancer.

C. BRAF V600 mutation positive colon cancer.

D. BRAF V600E mutation positive appendiceal adenocarcinoma.

E. BRAF V600E mutation positive recurrent or advanced NSCLC.

F. BRAF V600E mutation positive small bowel adenocarcinoma.

G. BRAF V600E mutation positive thyroid carcinomas (papillary, follicular, oncocytic, or anaplastic).

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- Treatment of wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Cutaneous melanoma, NSCLC, thyroid carcinoma (papillary, follicular, oncocytic, or anaplastic): 180 capsules per 30 days.
- CRC, Appendiceal adenocarcinoma: 120 capsules per 30 days.

Approval Length

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

- N/A

References

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4. National Comprehensive Cancer Network.Clinical Practice Guidelines in Oncology. Rectal cancer. Version 2.2026. Updated April 7, 2026. Accessed June 11, 2026.
5. National Comprehensive Cancer Network.Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. Version 5.2026. Updated March 13, 2026. Accessed June 11, 2026.
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8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Thyroid carcinoma. Version 2.2026. Updated June 2, 2026. Accessed June 11, 2026.
9. Schadendorf D, Dummer R, Flaherty KT, et al. COLUMBUS 7-year update: A randomized, open-label, phase III trial of encorafenib plus binimetinib versus vemurafenib or encorafenib in patients with BRAF V600E/K-mutant melanoma. *Eur J Cancer.* 2024;204:114073. doi: 10.1016/j.ejca.2024.114073
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12. Kopetz S, Tabernero J, Lonardi S, et al. A randomised study of encorafenib, cetuximab, and FOLFIRI versus FOLFIRI with or without bevacizumab in BRAF V600E-mutant colorectal cancer: BREAKWATER Cohort 3. *Ann Oncol.* 2026:S0923-7534(26)00179-1. doi: 10.1016/j.annonc.2026.04.017
13. Tahara M, Kiyota N, Imai H, et al. A Phase 2 Study of encorafenib in combination with binimetinib in patients with metastatic *BRAF*-mutated thyroid cancer in Japan. *Thyroid.* 2024 ;34(4):467-476. doi: 10.1089/thy.2023.0547. Erratum in: Thyroid. 2025;35(10):1209. doi: 10.1177/10507256251384793

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.