

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Braftovi Prior Authorization Policy

- Braftovi[®] (encorafenib capsules – Array BioPharma)

REVIEW DATE: 08/14/2024

OVERVIEW

Braftovi, a BRAF inhibitor, is indicated for the following uses:¹

- **Colorectal cancer**, in combination with Erbitux[®] (cetuximab intravenous infusion), for the treatment of metastatic disease and a *BRAF V600E* mutation, as detected by an FDA-approved test, after prior therapy in adults.
- **Melanoma**, in combination with Mektovi[®] (binimetinib tablets), for the treatment of unresectable or metastatic disease and a *BRAF V600E* or *V600K* mutation, as detected by an FDA-approved test in adults.
- **Non-small cell lung cancer (NSCLC)**, in combination with Mektovi, for the treatment of adult patients with metastatic NSCLC with a *BRAF V600E* mutation, as detected by an FDA-approved test.

It is a limitation of use that Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF colorectal cancer, or wild-type BRAF NSCLC.

Guidelines

National Comprehensive Cancer Network guidelines support use of Braftovi in the following cancers.⁵

- **Colon and Rectal Cancer:** Guidelines for colon cancer (version 4.2024 – July 3, 2024) and rectal cancer (version 3.2024 – July 3, 2024) recommend Braftovi for some situations in patients with *BRAF V600E*-mutated disease.³ For primary treatment (following adjuvant chemotherapy) or as subsequent use, Braftovi + Erbitux or Vectibix[®] (panitumumab intravenous infusion) is a recommended treatment option. NCCN Compendium recommends the use of Braftovi for appendiceal adenocarcinoma for *BRAF V600E* mutation-positive disease, as subsequent therapy, in combination with Erbitux or Vectibix.⁵
- **Melanoma, Cutaneous:** Guidelines (version 2.2024 – April 3, 2024) recommend BRAF/MEK inhibitor combinations among the “Preferred” therapies for first-line (category 1) and subsequent treatment (category 2A) of metastatic or unresectable melanoma with a *V600*-activating mutation.² The combinations are also recommended for adjuvant treatment (category 2B). While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor (Tafinlar[®] [dabrafenib capsules] or Zelboraf[®] [vemurafenib tablets]) is a recommended option, especially in patients who are not appropriate candidates for checkpoint immunotherapy.
- **Non-Small Cell Lung Cancer:** Guidelines (version 7.2024 – June 26, 2024) recommend Braftovi + Mektovi and Tafinlar + Mekinist[®] (trametinib tablets) combinations for first-line “Preferred” regimens and as subsequent therapies (both category 2A) for *BRAF V600E* mutation-positive disease.⁶ Zelboraf or Tafinlar monotherapy is also recommended under “Useful in Certain Circumstances” (both category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Braftovi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Braftovi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

- 1. Colon or Rectal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has *BRAF V600E* mutation-positive disease; AND
 - C) Patient has previously received a chemotherapy regimen for colon or rectal cancer; AND
Note: Examples of chemotherapy regimens include a fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine; oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin).
 - D) The medication is prescribed as part of a combination regimen for colon or rectal cancer.
Note: Examples of combination regimens include Braftovi + Erbitux (cetuximab intravenous infusion), Braftovi + Vectibix (panitumumab intravenous infusion).
- 2. Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has unresectable, advanced, or metastatic melanoma; AND
 - C) Patient has *BRAF V600* mutation-positive disease.
- 3. Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has *BRAF V600E* mutation-positive metastatic disease; AND
 - C) The medication will be taken in combination with Mektovi (binimetinib tablets).

Other Uses with Supportive Evidence

- 4. Appendiceal Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has *BRAF V600E* mutation-positive disease; AND
 - C) The medication will be used as subsequent therapy for advanced or metastatic disease; AND
 - D) The medication will be used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Braftovi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Braftovi® capsules [prescribing information]. Boulder, CO: Array BioPharma; October 2023.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on August 9, 2024.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – July 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on August 9, 2024.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – July 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on August 9, 2024.
5. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on August 9, 2024. Search terms: encorafenib.
6. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – June 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on August 9, 2024.