

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Braftovi Prior Authorization Policy

- Braftovi® (encorafenib capsules – Array BioPharma)

REVIEW DATE: 08/03/2022

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 adults with metastatic disease and a *BRAF V600E* mutation, as detected by an FDA-approved test, after prior therapy.
- **Melanoma**, in combination with Mektovi® (binimetinib tablets), for the treatment of adults with unresectable or metastatic disease and a *BRAF V600E* or *V600K* mutation, as detected by an FDA-approved test.

It is a limitation of use that Braftovi is not indicated for wild-type disease.

Guidelines

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

- **Colon and Rectal Cancer:** Guidelines for colon cancer (version 1.2022 – February 25, 2022) and rectal cancer (version 1.2022 – February 25, 2022) 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.
- **Melanoma, Cutaneous:** Guidelines (version 3.2022 – April 11, 2022) recommend BRAF/MEK inhibitor combinations among the preferred therapies for first-line and subsequent treatment of metastatic or unresectable melanoma with a *V600*-activating mutation.² 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. Tafinlar + Mekinist® (trametinib tablets) is also recommended in guidelines as adjuvant therapy (including for nodal recurrence) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection. If unacceptable toxicity to Tafinlar/Mekinist, other BRAF/MEK combinations can be considered.

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 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 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.

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; February 2022.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 3.2022 – April 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on July 30, 2022.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – February 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on July 30, 2022.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – February 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on July 30, 2022.