

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology – Braftovi Prior Authorization Policy
- Braftovi® (encorafenib capsules – Array BioPharma)

REVIEW DATE: 07/08/2020

OVERVIEW

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

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

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

Guidelines

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

- **Melanoma:** Guidelines (version 3.2020 – May 18, 2020) recommend BRAF/MEK inhibitor combinations for first-line (preferred if clinically needed for early response) 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, particularly if the patient is not a candidate for checkpoint immunotherapy. Following resection of limited metastatic disease with a *BRAF V600*-activating mutation, BRAF/MEK combination therapy is among the treatment options for patients with no evidence of disease. 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.
- **Colon and Rectal Cancer:** Guidelines for colon cancer (version 4.2020 – June 15, 2020) and rectal cancer (version 6.2020 – June 25, 2020) 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 IV infusion) is a recommended treatment option.

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 the following criteria:

FDA-Approved Indications

- 1. Melanoma.** Approve for 3 years if the patient meets BOTH of the following (A and B):
 - A) Patient has unresectable, advanced, or metastatic melanoma; AND
 - B) Patient has *BRAF V600* mutation-positive disease.

- 2. Colon or Rectal Cancer.** Approve for 3 years if the patient meets the following (A, B, and C):
 - A) Patient has *BRAF V600E* mutation-positive disease; AND
 - B) 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).
 - C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.
Note: Examples of combination regimens include Braftovi + Erbitux (cetuximab IV infusion), Braftovi + Vectibix (panitumumab IV 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; April 2020.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 3.2020 – May 18, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on July 2, 2020.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (Version 4.2020 – June 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on July 2, 2020.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (Version 6.2020 – June 25, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on July 2, 2020.