Prior Authorization
Oncology – Braftovi® (encorafenib capsules)

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Product Identifier(s)

61682

INSTRUCTIONS FOR USE
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National Formulary Medical Necessity

Cigna covers encorafenib (Braftovi®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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

FDA Indication(s)

1. **Colon or Rectal Cancer.** Approve for 1 year if the individual meets the following (A, B, C, and D):
   - **A)** Individual is ≥ 18 years of age; AND
   - **B)** Individual has *BRAF V600E* mutation-positive disease; AND
   - **C)** Individual 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 individual meets the following (A, B, and C):
A) Individual is ≥ 18 years of age; AND
B) Individual has unresectable, advanced, or metastatic melanoma; AND
C) Individual has *BRAF V600* mutation-positive disease.

Conditions Not Covered

Encorafenib (Braftovi®) is considered experimental, investigational or unproven for ANY other use.

Background

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.

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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Colon or Rectal Cancer:** A requirement was added that the patient is ≥ 18 years of age. **Melanoma:** A requirement was added that the patient is ≥ 18 years of age.	08/04/2021
Selected Revision	Approval durations were changed from 3 years to 1 year.	06/22/2022
Annual Revision	No criteria changes.	08/03/2022