MEDICAL MUTUAL®

Drug Policy

Policy:	Braftovi (encorafenib)	Annual Review Date: 01/18/2024 Last Revised Date: 01/18/2024

OVERVIEW

Braftovi, a BRAF inhibitor, is indicated in combination with Mektovi (binimetinib tablets), for the treatment of patients with unresectable or metastatic melanoma with 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 melanoma. Braftovi is also indicated in combination with Erbitux (cetuximab) for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation as detected by an FDA-approved test, after prior therapy.

POLICY STATEMENT

This policy involves the use of Braftovi. Prior authorization is recommended for pharmacy benefit coverage of Braftovi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Braftovi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Braftovi be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Braftovi must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

For Melanoma, BRAF V600 Mutation-Positive Disease: Approvals will be granted if the indication-specific criteria listed below are met AND the patient meets ONE of the following criteria. If the patient does not meet any of the following, offer to review for one of the preferred products (Zelboraf, Tafinlar) using the appropriate *Prior Authorization Policy*.

a) The patient has tried one of Zelboraf or Tafinlar; OR
b) The patient is currently receiving Braftovi

1. **Malignant Melanoma**
   Criteria. *Patient must meet the following criteria (A, B and C):*
   - **A.** The patient has unresectable, advanced, or metastatic disease; AND
   - **B.** The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test; AND
   - **C.** Braftovi will be used in combination with Mektovi (binimetinib)

2. **Colon or Rectal Cancer**
   Criteria. *Patient must meet the following criteria (A, B, C and D):*
   - **A.** The patient has unresectable, advanced, or metastatic disease; AND
   - **B.** The patient has a BRAF V600E mutation as detected by an FDA-approved test; AND
   - **C.** The patient has NOT been previously treated with cetuximab or panitumumab; AND
   - **D.** The patient has progressed on prior therapy (examples of prior therapy include FOLFOX [fluorouracil, leucovorin, oxaliplatin] or CapeOX (capecitabine, oxaliplatin); AND
   - **E.** Braftovi will be used in combination with Erbitux (cetuximab) or Vectibix (panitumumab)

3. **Non-Small Cell Lung Cancer (NSCLC)**
   Criteria. *Patient must meet the following criteria (A, B, C and D):*
   - **A.** The patient has a BRAF V600E mutation, as detected by an FDA-approved test; AND
   - **B.** Braftovi will be used in combination with Mektovi (binimetinib); AND
   - **C.** The patient has recurrent, advanced, or metastatic disease

4. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

5. **Patient has been started on Braftovi**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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Braftovi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Melanoma with Wild-Type BRAF Mutation.** In vitro experiments have demonstrated increased cell proliferation in BRAF wild-type cells which are exposed to BRAF inhibitors.

2. **Colon or Rectal Cancer with wild-type BRAF mutation.** In vitro experiments have demonstrated increased cell proliferation in BRAF wild-type cells which are exposed to BRAF inhibitors.

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Braftovi™ capsules [prescribing information]. Boulder, CO: Array BioPharma; February 2022.
2. Genetic Home Reference. BRAF gene. National Institutes of Health, US Department of Health & Human Service Web Site. Reviewed October 2017. Accessed on 16 July 2018. Available at: https://ghr.nlm.nih.gov/gene/BRAF.
3. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 2.2018 – January 19, 2018). National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 16 July 2018.
4. Encorafenib. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated 20 June 2023. Accessed on 22 June 2023.
5. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 15 January 2024.