Braftovi (encorafenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Braftovi (encorafenib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Braftovi (encorafenib) may be approved when the following criteria are met:

I. Individual has a diagnosis of unresectable or metastatic Melanoma (Label, NCCN 1, 2A); **AND**
   A. Individual is using in combination with binimetinib for disease with BRAF V600 activating mutation; **OR**
   B. Individual is using as a single agent due to unacceptable toxicities or intolerable side effect profiles with dabrafenib/trametinib inhibitor combination (NCCN 2A);

OR

II. Individual has limited resectable stage III cutaneous melanoma (NCCN 2A); AND
   A. Individual has either clinical satellite/in-transit metastases or local satellite/in-transit recurrence; **AND**
   B. Individual is using as initial treatment; **AND**
   C. Individual is using in combination with binimetinib for disease with BRAF V600 activating mutation and unacceptable toxicities or intolerable side effect profiles with dabrafenib/trametinib combination;

OR

III. Individual has a diagnosis of unresectable, advanced or metastatic Colon or Rectal (Colorectal) Cancer [CRC]; (Label, NCCN 2A); **AND**
   A. Individual is using in combination with either cetuximab or panitumumab; **AND**
   B. Individual has BRAF V600E mutation; **AND**
   C. Individual has demonstrated disease progression after one or more prior lines of systemic therapy; **AND**
   D. Individual has not previously failed treatment with cetuximab or panitumumab in a prior line of therapy for CRC;

OR

IV. Individual has a diagnosis of metastatic non-small cell lung cancer (NSCLC) (Label, NCT03915951); **AND**

A. Individual is using in combination with binimetinib for disease with BRAF V600E mutation; **AND**
B. Individual has received less than 1 prior line of systemic therapy in the advanced/metastatic setting; **AND**
C. Individual has not received prior treatment with any BRAF inhibitor (e.g. dabrafenib, vemurafenib) or MEK inhibitor (cobimetinib, selumetinib).

Braftovi (encorafenib) may not be approved for the following:

I. Individual is using for the treatment of wild-type BRAF melanoma or wild type BRAF colorectal cancer, or wild-type BRAF NSCLC.

Key References:

1. Corcoran RB, Andre T, Atreya CE, et al. Combined BRAF, EGFR, and MEK inhibition in Patients with BRAF V600E-Mutant Colorectal Cancer. Cancer Discov; 8(4); 428–43. 2018 AACR.
2. Corcoran RB, Atreya CE, Falchook GS, et al. Combined BRAF and MEK inhibition with dabrafenib and trametinib in BRAF V600-mutant colorectal cancer. J Clin Oncol. 2015; 33:4023-4031.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 28, 2023.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on September 28, 2023.
    a. Cutaneous Melanoma. V2.2023. Revised March 10, 2023.
    b. Colon Cancer. V3.2023. Revised September 21, 2023.
    c. Rectal Cancer. V5.2023. Revised September 21, 2023.
8. Van Cutsem E, Cyle P, Huijiberts S, et al. BEACON CRC study safety lead-in: assessment of the BRAF inhibitor encorafenib + MEK inhibitor binimetinib + anti-epidermal growth factor antibocy cetuximab for BRAF V600E metastatic colorectal cancer. *Ann Oncolo* 2018; 29 (supple 5; abst O-027).
9. Van Cutsem E, Huijberts S, Grothey A, et al. Binimetinib, Encorafenib, and Cetuximab Triplet Therapy for Patients with BRAF V600E-Mutant Metastatic Colorectal Cancer: Safety Lead-In Results from the Phase III Beacon Colorectal Cancer Study. J Clin Oncol 37:1460-1469. 2019 American Society of Clinical Oncology.