Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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 V600E or V600K mutation, with test result confirmed;
   OR
   B. Individual is using in combination with binimetinib *and* has a BRAF V600 activating mutation with test result confirmed;
      AND
      1. Using as first line, or subsequent therapy for disease progression;
         OR
      2. Using in re-induction therapy with disease control, but experiences disease progression/relapse > 3 months after treatment discontinuation;

OR

II. Individual has a diagnosis of unresectable advanced or metastatic Colon or Rectal (Colorectal) Cancer; (Label, NCCN 2A); **AND**
III. Individual is using in combination with either cetuximab or panitumumab; **AND**
IV. Individual has BRAF V600E mutation with test result confirmed; **AND**
V. Individual has demonstrated disease progression after one or more prior lines of systemic therapy; **AND**
VI. Individual has not been previously treated with cetuximab or panitumumab.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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.

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. Accessed on October 8, 2019.
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. Accessed on October 8, 2019.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: July 7, 2020.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 7, 2020.
    a. Cutaneous Melanoma. V3.2020. Revised May 18, 2020.
    b. Colon Cancer. V4.2020. Revised June 15, 2020.
    c. Rectal Cancer. V6.2020. Revised June 25, 2020.
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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.