

# POLICY Document for BRAFTOVI (encorafenib)

The overall objective of this policy is to support the appropriate and cost effective use of the medication. This document provides specific information to each section of the overall policy.

## Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

## Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

## Section 1: Clinical Criteria

### SPECIALTY GUIDELINE MANAGEMENT

#### BRAFTOVI (encorafenib)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indication

Braftovi is indicated, in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

Limitations of use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma.

##### B. Compendial Uses

1. Glioma, BRAF V600 activating mutation-positive
2. Meningioma, BRAF V600 activating mutation-positive
3. Astrocytoma, BRAF V600 activating mutation-positive
4. Colorectal cancer, BRAF V600E activating mutation-positive

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. DOCUMENTATION

Submission of BRAF mutation documentation is necessary to initiate the prior authorization review.

##### III. CRITERIA FOR INITIAL APPROVAL

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#### **A. Melanoma**

Authorization of 12 months may be granted for treatment of unresectable or metastatic melanoma when all of the following criteria are met:

1. Braftovi is used in combination with binimetinib (Mektovi)
2. Tumor is positive for BRAF V600E or V600K mutation.

#### **B. Central Nervous System Cancer**

Authorization of 12 months may be granted for treatment of BRAF V600 mutation-positive gliomas, meningiomas, or astrocytomas.

#### **C. Colorectal Cancer**

Authorization of 12 months may be granted for treatment of unresectable advanced or metastatic colorectal cancer when the following criteria are met:

1. Braftovi is used in combination with binimetinib (Mektovi) and either cetuximab or panitumumab
2. Tumor is positive for BRAF V600E mutation.
3. Will be used as subsequent therapy

### **IV. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continuation of therapy for an indication outlined in section III when there is no evidence of unacceptable toxicity or disease progression on the current regimen.

## **Section 2: Oncology Clinical Policy**

### **Oncology Clinical Policy**

#### **Program Description**

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives.<sup>1</sup> It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN templates are based on NCCN Clinical Practice Guidelines and NCCN Compendium. The NCCN Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

#### **NCCN Categories of Evidence and Consensus<sup>2</sup>**

- Category 1: Based on high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based on lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

## Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

This policy provides coverage of a regimen review when *all* of the following criteria are met:

- a. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal: <https://provider.carefirst.com/providers/home.page>
- b. If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
2. The prior authorization review is requested for an oncology drug or biologic that requires prior authorization on the medical benefit.
3. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include breast, lung, colon and rectal cancer.
4. The member is eligible for regimen review.

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Authorizations may be granted for 12 months.

Further review may be indicated where the above criteria are not met.

## Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

## Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia and/or evidence-based practice guidelines.

## REFERENCES:

### SECTION 1

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2. The NCCN Drugs & Biologics Compendium 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 30, 2019.
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4. Mordechai O, Postovsky S, Vlodayvsky E, et al. Metastatic Rhabdoid Meningioma with *BRAF* V600E Mutation and Good Response to Personalized Therapy: Case Report and Review of the Literature. *Pediatric Hematology and Oncology*. 2015; 32:3, 207-211, DOI: 10.3109/08880018.2014.936058
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## SECTION 2

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2. National Comprehensive Cancer Network. NCCN Categories of Evidence and Consensus website. [https://www.nccn.org/professionals/physician\\_gls/categories\\_of\\_consensus.aspx](https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx), accessed September 16, 2019.
3. National Comprehensive Cancer Network. NCCN Guidelines website. [http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp), accessed September 16, 2019. (Note: An account may be required.)
4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium® website. [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp), accessed September 16, 2019. (Note: A subscription may be required.)
5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. <https://www.nccn.org/professionals/OrderTemplates/Default.aspx>, accessed September 16, 2019. (Note: A subscription may be required.)