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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	July 13, 2018
<b>Subject:</b>	Braftovi	<b>Page:</b>	1 of 5

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**Last Review Date:** December 8, 2023

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## Braftovi

### Description

#### Braftovi (encorafenib)

#### Background

Braftovi (encorafenib) is a kinase inhibitor indicated for the treatment of patients with certain cancers with BRAF mutations. Mutations in the BRAF gene, such as BRAF V600E, can result in constitutively activated BRAF kinases that may stimulate tumor cell growth. Braftovi targets BRAF V600E as well as other kinases and inhibits the activity of these kinases, thereby inhibiting tumor growth and proliferation (1).

#### Regulatory Status

FDA-approved indications: Braftovi is a kinase inhibitor indicated: (1)

- 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
- In combination with 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
- In combination with binimetinib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test

Limitations of Use: (1)

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	July 13, 2018
<b>Subject:</b>	Braftovi	<b>Page:</b>	2 of 5

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Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC.

Confirmation of the presence of BRAF V600E or V600K mutation in tumor specimens prior to the initiation of Braftovi. New primary malignancies, cutaneous and non-cutaneous can occur during therapy as well as major hemorrhagic events, uveitis, embryo-fetal toxicity, and QT prolongation. Prescribers must monitor for these adverse events and adjust the dosage, interrupt, or discontinue therapy as indicated (1).

Safety and effectiveness of Braftovi in pediatric patients have not been established (1).

#### Related policies

Cotellic, Mekinist, Mektovi, Tafinlar, Zelboraf

#### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Braftovi may be considered **medically necessary** if the conditions indicated below are met.

Braftovi may be considered **investigational** for all other indications.

### Prior-Approval Requirements

**Age** 18 years of age or older

#### Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic melanoma
  - a. Used in combination with Mektovi (binimetinib)
  - b. Documented BRAF V600E or BRAF V600K mutation as detected by an FDA-approved test
  - c. Patient must **NOT** have wild-type BRAF melanoma
2. Metastatic colorectal cancer (CRC)

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	July 13, 2018
<b>Subject:</b>	Braftovi	<b>Page:</b>	3 of 5

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- a. Used in combination with Erbitux (cetuximab)
- b. Documented BRAF V600E mutation as detected by an FDA-approved test
- c. Patient must **NOT** have wild-type BRAF CRC
- d. **NOT** used as first-line therapy
- 3. Metastatic non-small cell lung cancer (NSCLC)
  - a. Used in combination with Mektovi (binimetinib)
  - b. Documented BRAF V600E mutation as detected by an FDA-approved test
  - c. Patient must **NOT** have wild-type BRAF NSCLC

**AND ALL** of the following for **ALL** indications:

- 1. Physician agrees to perform dermatologic evaluations every 2 months while on therapy and up to 6 months following discontinuation of therapy
- 2. Prescriber agrees to monitor for the following:
  - a. Tumor promotion in BRAF Wild-Type Tumors
  - b. Hemorrhage
  - c. Uveitis
  - d. QT prolongation
  - e. Embryo-fetal toxicity

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

- 1. Unresectable or metastatic melanoma
  - a. Used in combination with Mektovi (binimetinib)
- 2. Metastatic colorectal cancer (CRC)
  - a. Used in combination with Erbitux (cetuximab)
- 3. Metastatic non-small cell lung cancer (NSCLC)
  - a. Used in combination with Mektovi (binimetinib)

**AND ALL** of the following for **ALL** indications:

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	July 13, 2018
<b>Subject:</b>	Braftovi	<b>Page:</b>	4 of 5

1. Physician agrees to perform dermatologic evaluations every 2 months while on therapy and up to 6 months following discontinuation of therapy
2. **NO** disease progression or unacceptable toxicity
3. Prescriber agrees to monitor for the following:
  - a. Tumor promotion in BRAF Wild-Type Tumors
  - b. Hemorrhage
  - c. Uveitis
  - d. QT prolongation
  - e. Embryo-fetal toxicity

### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Quantity** 540 capsules per 90 days

**Duration** 12 months

#### Prior – Approval *Renewal* Limits

Same as above

### Rationale

#### Summary

Braftovi (encorafenib) is a kinase inhibitor indicated for the treatment of patients with certain cancers with BRAF mutations. Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to the initiation of Braftovi. New primary malignancies, cutaneous and non-cutaneous can occur during therapy as well as major hemorrhagic events, uveitis, embryo-fetal toxicity, and QT prolongation. Prescribers must monitor for these adverse events and adjust the dosage, interrupt, or discontinue therapy as indicated. Safety and effectiveness of Braftovi in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Braftovi while maintaining optimal therapeutic outcomes.

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	July 13, 2018
<b>Subject:</b>	Braftovi	<b>Page:</b>	5 of 5

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## References

1. Braftovi [package insert]. Boulder, CO: Array BioPharma Inc.; October 2023.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Encorafenib 2023. National Comprehensive Cancer Network, Inc. Accessed on November 2, 2023.

## Policy History

Date	Action
July 2018	Addition to PA
September 2018	Annual review Addition of prescriber agreement to monitor for tumor promotion in BRAF Wild-Type Tumors, hemorrhage, uveitis, QT prolongation, and embryo-fetal toxicity per SME
June 2019	Annual editorial review and reference update, Revised quantity
April 2020	Addition of indication: metastatic colorectal cancer
June 2020	Annual review
March 2021	Annual editorial review
March 2022	Annual review and reference update
March 2023	Annual review and reference update
June 2023	Annual review and reference update
November 2023	Per PI update, added indication of NSCLC
December 2023	Annual review and reference update

## Keywords

**This policy was approved by the FEP<sup>®</sup> Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.**