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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 13, 2018
Subject:	Braftovi	**Page:**	1 of 5

Last Review Date: March 12, 2021

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

Limitations of use: (1)
Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC.

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** for patients 18 years of age or older for the treatment of melanoma or colorectal cancer and if the conditions indicated below are met.

Braftovi may be considered **investigational** in patients less than 18 years of age and 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)
    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

AND ALL of the following:

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)

AND ALL of the following:

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.

References

1. Braftovi [package insert]. Boulder, CO: Array BioPharma Inc.; April 2020.

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

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.