BlueCross BlueShield Federal Employee Program

BRAFTOVI (encorafenib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 and mFOLFOX6, for the treatment of patients with metastatic colorectal cancer (mCRC) with a BRAF V600E 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)

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

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 cardiomyopathy, hepatotoxicity, major hemorrhagic events, uveitis, and QT prolongation. Prescribers must monitor for these adverse events and adjust the dosage, interrupt, or discontinue therapy as indicated (1).

Braftovi may cause embryo-fetal toxicity when administered to a pregnant woman. Advise pregnant

women and females or reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use an effective nonhormonal method of contraception since Braftovi can render hormonal contraceptives ineffective, during treatment and for 2 weeks after the last dose (1).

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

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.; December 2024.
2. NCCN Drugs & Biologics Compendium® Encorafenib 2025. National Comprehensive Cancer Network, Inc. Accessed on February 3, 2025.