



MEKTOVI (binimetinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Mektovi (binimetinib) is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma or metastatic non-small cell lung cancer (NSCLC). Mektovi works upstream in the RAS/RAF/MEK/ERK pathway by reversibly inhibiting mitogen-activated extracellular signal regulated kinase 1 (MEK1) and MEK2 activity. MEK proteins can phosphorylate BRAF-mutant human melanoma cell lines, which activates tumor growth. By inhibiting MEK proteins, Mektovi can inhibit the activation of BRAF-mutant human melanoma cell lines, decreasing tumor growth (1).

Mektovi (binimetinib) is to be used in combination with Braftovi (encorafenib). Mektovi and Braftovi target two different kinases in the RAS/RAF/MEK/ERK pathway. Co-administration results in greater anti-proliferative activity in vitro in BRAF mutation-positive cell lines and greater anti-tumor activity with respect to tumor growth inhibition in BRAF V600E mutant human melanoma (1).

Regulatory Status

FDA-approved indication: Mektovi is a kinase inhibitor indicated (1):

- In combination with encorafenib, 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 encorafenib, 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.

Confirm the presence of a BRAF V600E or V600K mutation in tumor specimens prior to initiating Mektovi. Patients should be monitored for the development of new malignancies, cardiomyopathy, venous thromboembolism, ocular toxicities, interstitial lung disease, hepatotoxicity, rhabdomyolysis, embryo-fetal toxicity, and hemorrhagic events throughout therapy. Prescribers must monitor for these adverse events and adjust the dosage, interrupt, or discontinue therapy as indicated (1).

Lastly, Mektovi can cause fetal harm when administered to pregnant women. Females of



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reproductive potential should be counseled to use effective contraception during treatment with Mektovi and for at least 30 days after the final dose (1).

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

Summary

Mektovi (binimetinib) is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma or metastatic NSCLC. Confirm the presence of a BRAF V600E or V600K mutation in tumor specimens prior to initiating Mektovi. Patients should be monitored for the development of new malignancies, cardiomyopathy, venous thromboembolism, ocular toxicities, interstitial lung disease, hepatotoxicity, rhabdomyolysis, embryo-fetal toxicity, and hemorrhagic events throughout therapy. Prescribers must monitor for these adverse events and adjust the dosage, interrupt, or discontinue therapy as indicated (1).

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

References

1. Mektovi [package insert]. Boulder, CO: Array BioPharma Inc.; October 2023.
2. NCCN Drugs & Biologics Compendium® Binimetinib 2024. National Comprehensive Cancer Network, Inc. Accessed on April 15, 2024.