Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Mektovi (binimetinib)

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Origination: 12/2018
Last Review: 12/2018
Next Review: 12/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Mektovi (binimetinib)** when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Mektovi (binimetinib) may be considered **medically necessary** when all of the following criteria are met:

FDA-Approved Indications

1. **Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** The patient has unresectable, advanced, or metastatic melanoma; AND
   - **B)** The patient has the BRAF V600 mutation; AND
   - **C)** Mektovi will be used in combination with Braftovi (encorafenib capsules).

NCCN guidelines for melanoma (updated prior to approval of Braftovi + Mektovi) recommend other BRAF + MEK inhibitor combinations (e.g., Zelboraf + Cotellic, Tafinlar + Mekinist) for first-line and subsequent treatment of melanoma with a V600 activating mutation.[3] The prescribing information for Mektovi states that if Braftovi is permanently discontinued, Mektovi should also be stopped.[1]

When Policy Topic is not covered

Mektovi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions and may be considered **investigational.** (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Considerations

Mektovi (binimetinib) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service

Mektovi, a kinase inhibitor, is indicated in combination with Braftovi™ (encorafenib capsules) for treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation as detected by an FDA-approved test.[1] Some mutations in the BRAF gene can result in constitutively activated BRAF kinases that may stimulate tumor cell growth. Mektovi is a reversible inhibitor of mitogen-activated protein kinase (MAPK)/MEK1 and MEK2. Some mutations (e.g., V600E) in the BRAF gene can result in constitutively activated BRAF kinases that may stimulate tumor cell growth and lead to activation of the BRAF pathway, including MEK1 and MEK2.

Disease Overview

Mutations in the BRAF gene are common in several types of cancer.[2] The BRAF protein is normally switched on and off in response to signals that control cell growth and development; however, mutations cause the BRAF protein to be continuously active. This over activity may contribute to the growth of cancers by allowing abnormal cells to grow and divide uncontrollably. The V600E mutation is the most common BRAF gene mutation identified in cancers, particularly in melanoma.

Rationale

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

References

1. Mektovi® tablets [prescribing information]. Boulder, CO: Array BioPharma; June 2018.
2. Genetic Home Reference. BRAF gene. National Institutes of Health, US Department of Health & Human Services Web Site. Reviewed October 2017. Accessed on May 16, 2018. Available at: https://ghr.nlm.nih.gov/gene/BRAF.
3. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 2.2018 – January 19, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 16, 2018.

Billing Coding/Physician Documentation Information

NA Mektovi is a pharmacy benefit

Additional Policy Key Words

N/A

Policy Implementation/Update Information

12/2018 New policy titled Mektovi (binimetinib)