MEDICAL MUTUAL®

Drug Policy

Policy:	Mektovi (binimetinib)	Annual Review Date: 01/18/2024 Last Revised Date: 01/18/2024

OVERVIEW

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. 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. Mektovi is a reversible inhibitor of mitogen-activated protein kinase (MAPK)/MEK1 and MEK2.

POLICY STATEMENT

This policy involves the use of Mektovi. Prior authorization is recommended for pharmacy benefit coverage of Mektovi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Mektovi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Mektovi be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Mektovi must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mektovi is recommended in those who meet the following criteria:

For Melanoma, BRAF V600 Mutation-Positive Disease: Approvals will be granted if the indication-specific criteria listed below are met AND the patient meets ONE of the following criteria. If the patient does not meet any of the following, offer to review for one of the preferred products (Cotellic, Mekinist) using the appropriate *Prior Authorization Policy*.

a) The patient has tried one of Cotellic or Mekinist; OR
b) The patient is currently receiving Mektovi

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1. **Malignant Melanoma**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient has unresectable, advanced, or metastatic disease; AND
   - **B.** The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test; AND
   - **C.** Mektovi will be used in combination with Braftovi (encorafenib)

2. **Langerhans Cell Histiocytosis**
   Criteria. *Approve if Mektovi will be used as a single agent.*

3. **Ovarian/Fallopian Tube/Primary Peritoneal Cancer**
   Criteria. *Approve if Mektovi will be used as a single agent for recurrent disease*

4. **Gastrointestinal Stromal Tumors (GIST)**
   Criteria. *Patient must meet the following criteria*
   - **A.** Mektovi will be used in combination with imatinib as first-line therapy; AND
   - **B.** The patient meets one of the following:
     - **a.** The patient has SDH-deficient GIST; OR
     - **b.** The patient has unresectable primary disease; OR
     - **c.** The patient has had tumor rupture; OR
     - **d.** The patient has recurrent or metastatic disease.

5. **Non-Small Cell Lung Cancer (NSCLC)**
   Criteria. *Patient must meet the following criteria*
   - **A.** Mektovi will be used in combination with Braftovi (encorafenib) as first-line therapy; AND
   - **B.** The patient has recurrent, advanced, or metastatic disease; AND
   - **C.** The patient has a BRAF V600E mutation, as detected by an FDA-approved test.

6. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

7. **Patient has been started on Mektovi**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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. (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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Mektovi® tablets [prescribing information]. Boulder, CO: Array BioPharma; January 2019.
2. Genetic Home Reference. BRAF gene. National Institutes of Health, US Department of Health & Human Service Web Site. Reviewed October 2017. Accessed on 16 July 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). National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 16 July 2018.
4. Binimetinib. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated 21 May 2019. Accessed on 16 July 2019.
5. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 15 January 2024.