PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Mektovi Prior Authorization Policy
- Mektovi® (binimetinib tablets – Array BioPharma)

REVIEW DATE: 08/14/2024

OVERVIEW

Mektovi, a kinase inhibitor, is indicated for the following uses: [1]

- **Melanoma,** in combination with Braftovi® (encorafenib capsules) for the treatment of patients with unresectable or metastatic disease with a *BRAF V600E* or *V600K* mutation as detected by an FDA-approved test.
- **Non-small cell lung cancer (NSCLC),** in combination with Braftovi, for the treatment of adult patients with metastatic NSCLC with a *BRAF V600E* mutation, as detected by an FDA-approved test.

Guidelines

National Comprehensive Cancer Network guidelines support use of Mektovi in the following cancers.

- **Histiocytic Neoplasms:** Guidelines (version 2.2024 – July 19, 2024) recommend Cotellic® (cobimetinib tablets) "Preferred" or Mektovi as one of the "Other Recommended Regimens" (category 2A) for histiocytic neoplasms (if there is a MAP kinase pathway mutation, or no detectable mutation, or testing is not available) for the following types: Langerhans cell histiocytosis (including multisystem, pulmonary, or central nervous system lesions).[3]
- **Melanoma, Cutaneous:** Guidelines (version 2.2024 – April 3, 2024) recommend BRAF/MEK inhibitor combinations among the "Preferred" therapies for first-line (category 1) and subsequent treatment (category 2A) of metastatic or unresectable melanoma with a *V600* activating mutation.[2] This combination is also recommended for adjuvant treatment (category 2B). Mektovi as a single agent is a category 2B recommendation for NRAS-mutated tumors (for progression following immune checkpoint inhibitor therapy). While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor is an option, especially in patients who are not appropriate candidates for checkpoint immunotherapy.
- **Non-Small Cell Lung Cancer:** Guidelines (version 7.2024 – June 26, 2024) recommend Braftovi + Mektovi and Tafinlar® (dabrafenib capsules) + Mekinist® (trametinib tablets) for first-line "Preferred" regimens and as subsequent therapies (both category 2A) for *BRAF V600E* mutation-positive disease.[4] Zelboraf® (vemurafenib tablets) or Tafinlar monotherapy is also recommended under "Useful in Certain Circumstances" (both category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Mektovi. All approvals are provided the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable, advanced, or metastatic melanoma; AND
   - **C)** Patient has *BRAF V600* mutation-positive disease; AND
   - **D)** The medication will be used in combination with Braftovi (encorafenib capsules).

2. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has *BRAF V600E* mutation-positive metastatic disease; AND
   - **C)** The medication will be taken in combination with Braftovi (encorafenib capsules).

Other Uses with Supportive Evidence

3. **Histiocytic Neoplasm.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has Langerhans cell histiocytosis and meets ONE of the following (i, ii, or iii):
     - **i.** Multisystem disease; OR
     - **ii.** Pulmonary disease; OR
     - **iii.** Central nervous system lesions.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Mektovi is not recommended in the following situations:

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

REFERENCES

1. Mektovi® tablets [prescribing information]. Boulder, CO: Array BioPharma; October 2023.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 9, 2024.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 9, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – June 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 9, 2024.