VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/19/2023; selected revision 10/18/2023

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 1.2022 – May 20, 2022) recommend Cotellic® (cobimetinib tablets) "preferred" or Mektovi as "other recommended regimen" 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 2.2023 – March 10, 2023) recommend BRAF/MEK inhibitor combinations among the "preferred" therapies for first-line and subsequent treatment 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 3.2023 – April 13, 2023) recommend Tafinlar® (dabrafenib capsules) + Mekinist® (trametinib tablets) for first-line "preferred" and subsequent therapy (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). Braftovi + Mektovi combination is not yet addressed in the guidelines.

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 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 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 the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has Langerhans cell histiocytosis and 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 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 14, 2023.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 14, 2023.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on October 16, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Histiocytic Neoplasm:** To align with NCCN guidelines, this indication was added to the policy.	08/03/2022
Annual Revision	No criteria changes	07/19/2023
Selected Revision	**Non-Small Cell Lung Cancer:** Added new FDA-approved indication and criteria	10/18/2023