PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/03/2022

OVERVIEW

Mektovi, a kinase inhibitor, is indicated in combination with Braftovi® (encorafenib capsules) for treatment of adults with unresectable or metastatic **melanoma** with a *BRAF V600E* or *V600K* mutation as detected by an FDA-approved test.[1]

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® (preferred) or Mektovi (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 3.2022 – April 11, 2022) 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] While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor is an option. Tafinlar® (dabrafenib capsules) + Mekinist® (trametinib tablets) is also recommended in guidelines as adjuvant therapy (including for nodal recurrence) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection. If unacceptable toxicity to Tafinlar/Mekinist, other BRAF/MEK combinations can be considered.

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).

Other Uses with Supportive Evidence

2. **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; January 2019.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 3.2022 – April 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 30, 2022.
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 30, 2022.
4. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – July 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 30, 2022.