PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/15/2020

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.[1]

Guidelines

Guidelines (version 3.2020 – May 18, 2020) recommend BRAF/MEK inhibitor combinations for first-line (preferred if clinically needed for early response) 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 (Tafinlar® [dabrafenib capsules] or Zelboraf® [vemurafenib tablets]) is a recommended option, particularly if the patient is not a candidate for checkpoint immunotherapy. Following resection of limited metastatic disease with a *BRAF V600*-activating mutation, BRAF/MEK combination therapy is among the treatment options for patients with no evidence of disease. Tafinlar + 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 the following criteria:

FDA-Approved Indications

1. **Melanoma.** Approve for 3 years if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient has unresectable, advanced, or metastatic melanoma; AND
   - **B)** Patient has *BRAF V600* mutation-positive disease; AND
   - **C)** Mektovi will be used in combination with Braftovi (encorafenib capsules).

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 3.2020 – May 18, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2020.