Mektovi (binimetinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Mektovi (binimetinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mektovi (binimetinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of unresectable or metastatic melanoma; **AND**
   A. Individual is using in combination with encorafenib; **AND**
   B. Individual has tested for either BRAF V600E or V600K mutation (or BRAF V600 activating mutation);

OR

II. Individual has limited resectable stage III cutaneous melanoma (NCCN 2A); **AND**
   A. Individual has either clinical satellite/in-transit metastases or local satellite/in-transit recurrence; **AND**
   B. Individual is using as initial treatment; **AND**
   C. Individual is using in combination with encorafenib for disease with BRAF V600 activating mutation and unacceptable toxicities or intolerable side effect profiles with dabrafenib/trametinib combination;

OR

III. Individual has a diagnosis of Langerhans Cell Histiocytosis (NCCN 2A); **AND**
   A. Individual has mitogen-activated protein (MAP) kinase pathway mutation, or no other detectable/actionable mutation, or testing available; **AND**
   B. If cobimetinib or trametinib are intolerable; **AND**
   C. Individual is using as a single-agent;

OR

IV. Individual has a diagnosis of metastatic non-small cell lung cancer (NSCLC) (Label, NCT03915951); **AND**
   A. Individual is using in combination with encorafenib for disease with BRAF V600E mutation; **AND**
   B. Individual has received less than 1 prior line of systemic therapy in the advanced/metastatic setting; **AND**
   C. Individual has not received prior treatment with any BRAF inhibitor (e.g. dabrafenib, vemurafenib) or MEK inhibitor (cobimetinib, selumetinib).

Key References:

1. Aaroe A, Kurzrock R, Goyal G, et al. Successful treatment of non-langerhans cell histiocytosis with the MEK inhibitor Trametinib: a multicenter analysis. Blood Adv 2023;online ahead of print PMID:36857436.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 4, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 4, 2023.
    a. Cutaneous Melanoma. V2.2023. Revised March 10, 2023.
    b. Gastrointestinal Stromal Tumors. V1.2023. Revised March 13, 2023.
    c. Histiocytic Neoplasms. V1.2023. Revised August 11, 2023.
    d. Ovarian Cancer. V2.2023. Revised June 2, 2023

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.