

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 (Label, NCCN 1, 2A); **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 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, NCCN 2A); **AND**
 - A. Individual is using in combination with encorafenib for disease with BRAF V600E mutation; **AND**
 - B. Individual is treatment naïve or had been previously treated with 1 prior line of systemic therapy in the advanced/metastatic setting; **AND**
 - C. Individual has not received prior treatment with any BRAF inhibitors (e.g. dabrafenib, vemurafenib) or MEK inhibitors (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.: 2024. 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: September 30, 2024.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 30, 2024.
 - a. Ampullary Adenocarcinoma. V2.2024. Revised August 02, 2024.
 - b. Biliary Tract Cancers. V4.2024. Revised August 29, 2024.
 - c. Central Nervous System Cancers. V3.2024. Revised September 30, 2024.
 - d. Cutaneous Melanoma. V2.2023. Revised March 10, 2023.
 - e. Esophageal and Esophagogastric Junction Cancers. V4.2024. Revised July 30, 2024.
 - f. Gastric Cancer. V4.2024. Revised August 12, 2024.
 - g. Gastrointestinal Stromal Tumors. V2.2024. Revised July 31, 2024.
 - h. Hairy Cell Leukemia. V1. 2025. Revised September 26, 2024.
 - i. Head and Neck Cancers. V4. 2024. Revised May 1, 2024.
 - j. Histiocytic Neoplasms. V2.2024. Revised July 19, 2024.
 - k. Cutaneous Melanoma. V3.2024. Revised September 23, 2024.
 - l. Uveal Melanoma. V1. 2024. Revised May 23, 2024.
 - m. Neuroendocrine and Adrenal Tumors. V2.2024. Revised August 1, 2024.
 - n. Non-Small Cell Lung Cancer. V10.2024. Revised September 23, 2024.
 - o. Occult Primary. V2.2025. September 11, 2024.
 - p. Ovarian Cancer. V3.2024. Revised July 15, 2024.
 - q. Pancreatic Cancer. V3.2024. Revised August 02, 2024.
 - r. Pediatric Central Nervous System Cancers. V1.2024. Revised February 26, 2024.
 - s. Small Bowel Adenocarcinoma. V5.2024. Revised September 13, 2024.
 - t. Thyroid Carcinoma. V4.2024. Revised August 19, 2024.

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

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