MEDICATION POLICY:
Mektovi

Generic Name: binimetinib

Therapeutic Class or Brand Name: MEK Inhibitor

Applicable Drugs (if Therapeutic Class):
Mektovi (binimetinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/9/2019

Date Last Reviewed / Revised: 6/4/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indication(s)

A. Unresectable or metastatic melanoma
   1. Documentation of BRAF V600E or V600K mutations.
   2. Used in combination with Braftovi (encorafenib).

B. Metastatic non-small cell lung cancer (NSCLC)
   1. Documentation of BRAF V600E mutation.
   2. Used in combination with Braftovi (encorafenib).

Other Uses With Supportive Evidence

A. BRAF V600 mutation positive cutaneous melanoma.

B. BRAF V600E mutation positive recurrent or advanced NSCLC.

C. Adult or pediatric Langerhans cell histiocytosis.

D. BRAF V600E mutation positive thyroid carcinomas (papillary, follicular, oncocytic, or anaplastic).

II. Minimum age requirement:

A. 18 years old: cutaneous melanoma, NSCLC, thyroid carcinoma (papillary, follicular, oncocytic, or anaplastic).

B. Birth: Langerhans cell histiocytosis.

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- Treatment of wild-type BRAF melanoma or wild-type BRAF NSCLC.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- 180 tablets per 30 days

Approval Length

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

- N/A

References

1. Mektovi. Prescribing information. Pflizer Inc; March 2025. Accessed June 4, 2026. http://labeling.pfizer.com/ShowLabeling.aspx?id=12988
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Melanoma: Cutaneous. Version2.2026. Updated April 17, 2026. Accessed June 4, 2026.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. Version 5.2026. Updated March 13, 2026. Accessed June 4, 2026.
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version1.2026. Updated May 8,2026. Accessed June 4, 2026.
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. Version 2.2026. Updated June 2, 2026. Accessed June 4, 2026.
6. Schadendorf D, Dummer R, Flaherty KT, et al. COLUMBUS 7-year update: A randomized, open-label, phase III trial of encorafenib plus binimetinib versus vemurafenib or encorafenib in patients with BRAF V600E/K-mutant melanoma. *Eur J Cancer.* 2024;204:114073. doi: 10.1016/j.ejca.2024.114073
7. Riely GJ, Ahn MJ, Clarke JM, et al. Updated efficacy and safety from the phase 2 PHAROS study of encorafenib plus binimetinib in patients with BRAF V600E-mutant metastatic NSCLC-A Brief Report. *J Thorac Oncol*. 2025;20(10):1538-1547. doi: 10.1016/j.jtho.2025.05.023

8. Ballester LY, Cantu MD, Lim KPH, et al. The use of BRAF V600E mutation-specific immunohistochemistry in pediatric Langerhans cell histiocytosis. *Hematol Oncol.* 2018;36(1):307-315. doi: 10.1002/hon.2388
9. Tahara M, Kiyota N, Imai H, et al. A Phase 2 Study of Encorafenib in Combination with Binimetinib in Patients with Metastatic *BRAF*-Mutated Thyroid Cancer in Japan. *Thyroid.* 2024 ;34(4):467-476. doi: 10.1089/thy.2023.0547. Erratum in: *Thyroid.* 2025;35(10):1209. doi: 10.1177/10507256251384793

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.