Reference number(s)
2612-A

Specialty Guideline Management
Mektovi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Mektovi	binimetinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

- Mektovi is indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.
- Mektovi is indicated, in combination with encorafenib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test.

Compendial Uses[2-7]

- Cutaneous Melanoma
- Non-Small Cell Lung Cancer (NSCLC)
- Central Nervous System Cancer

  - Glioma, BRAF V600 activating mutation-positive
  - Meningioma, BRAF V600 activating mutation-positive
  - Astrocytoma, BRAF V600 activating mutation-positive
- Langerhans Cell Histiocytosis

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of BRAF or NRAS mutation documentation is necessary to initiate the prior authorization review, where applicable.

Coverage Criteria

Cutaneous Melanoma[1-3]

Authorization of 12 months may be granted for treatment of cutaneous melanoma in any of the following settings:

- Unresectable or metastatic disease with a BRAF V600 activating mutation (e.g., V600E or V600K) when used in combination with encorafenib (Braftovi).
- Neoadjuvant treatment of stage III BRAF V600 mutation-positive cutaneous melanoma in combination with encorafenib (Braftovi) if immunotherapy is contraindicated when the member has had an unacceptable toxicity to dabrafenib (Tafinlar) in combination with trametinib (Mekinist) or dabrafenib/trametinib are less desirable based on side-effect profiles.
- Adjuvant treatment of resected stage III disease with a BRAF V600 activating mutation (e.g., V600E or V600K) in combination with encorafenib (Braftovi) when the member has had an unacceptable toxicity to dabrafenib (Tafinlar) in combination with trametinib (Mekinist) or dabrafenib/trametinib are less desirable based on side-effect profiles.
- Limited resectable local satellite/in-transit recurrent disease with a BRAF V600 activating mutation (e.g., V600E or V600K) in combination with encorafenib (Braftovi) when the member has had an unacceptable toxicity to dabrafenib (Tafinlar) in combination with trametinib (Mekinist) or dabrafenib/trametinib are less desirable based on side-effect profiles.
- Locally advanced unresectable or metastatic NRAS-mutant melanoma, as a single agent, when the member is previously untreated or has experienced disease progression on or after prior immunotherapy.

Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 12 months may be granted for treatment of BRAF V600E mutation-positive recurrent, advanced, or metastatic NSCLC in combination with encorafenib (Braftovi) when the member has not experienced disease progression on BRAF-targeted therapy.

Central Nervous System Cancer[4-7]

Authorization of 12 months may be granted for treatment of BRAF V600 mutation-positive (e.g., BRAF V600E or V600K) gliomas, meningiomas, or astrocytomas.

Langerhans Cell Histiocytosis[2]

Authorization of 12 months may be granted as a single agent for treatment of Langerhans cell histiocytosis, if cobimetinib or trametinib are not tolerated.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Mektovi [package insert]. Boulder, CO: Array BioPharma, Inc.; March 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed October 7, 2025.
3. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. http://online.lexi.com. Accessed October 29, 2025.
4. Usubalieva A, Pierson CR, Kavran CA, et al. Primary Meningeal Pleomorphic Xanthoastrocytoma With Anaplastic Features: A Report of 2 Cases, One With BRAFV600E Mutation and Clinical Response to the BRAF Inhibitor Dabrafenib. Journal of neuropathology and experimental neurology. 2015;74(10):960-969. doi:10.1097/NEN.0000000000000240.
5. Mordechai O, Postovsky S, Vlodavsky E, et al. Metastatic Rhabdoid Meningioma with BRAF V600E Mutation and Good Response to Personalized Therapy: Case Report and Review of the Literature. Pediatric Hematology and Oncology. 2015; 32:3, 207-211, DOI: 10.3109/08880018.2014.936058.
6. Lassaletta, A, Guerreiro Stucklin, A, Ramaswamy, V, et al. Profound clinical and radiological response to BRAF inhibition in a 2-month-old diencephalic child with hypothalamic/chiasmatic glioma. Pediatric Blood and Cancer. 2016; 63: 2038-2041. doi:10.1002/pbc.26086.
7. Meletah SK, Pavlick D, Brennan T, et al. Personalized Treatment for a Patient with a BRAF V600E Mutation using Dabrafenib and a Tumor Treatment Fields Device in a High-Grade Glioma Arising from Ganglioglioma. Journal of the National Comprehensive Cancer Network. 2016; 14(11): 1345-1350.