

Clinical Policy: Binimetinib (Mektovi)

Reference Number: ERX.SPA.248

Effective Date: 09.01.18

Last Review Date: 05.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Binimetinib (Mektovi[®]) is a kinase inhibitor.

FDA Approved Indication(s)

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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Mektovi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Melanoma (must meet all):

1. Diagnosis of melanoma with BRAF V600E or V600K mutation;
2. Disease is unresectable or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age \geq 18 years;
5. Prescribed in combination with Braftovi[™];
6. Request meets one of the following (a or b):*
 - a. Dose does not exceed 90 mg (6 tablets) per day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Medicaid – 6 months

Commercial – Length of Benefit

B. Colon Cancer, Rectal Cancer (off-label) (must meet all):

1. Diagnosis of colon cancer or rectal cancer with BRAF V600E mutation;
2. Disease is unresectable, advanced, or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age \geq 18 years;
5. Prescribed in combination with Braftovi and either Erbitux[®] or Vectibix[®];
6. One of the following (a or b):
 - a. Member previously received adjuvant therapy (e.g., FOLFOX, CapeOX);
 - b. Request is for subsequent therapy following previous treatment (e.g., oxaliplatin or irinotecan based therapy);
7. Request meets one of the following (a or b):*
 - a. Dose does not exceed 90 mg (6 tablets) per day;

- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Medicaid – 6 months

Commercial – Length of Benefit

C. Other diagnoses/indications

- 1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all):

- 1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Mektovi for a covered indication and has received this medication for at least 30 days;
- 2. Member is responding positively to therapy;
- 3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 90 mg (6 tablets) per day;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Medicaid – 12 months

Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):

- 1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

- 2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BRAF: B-Raf proto-oncogene, serine/threonine kinase

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria.

The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
FOLFOX (fluorouracil, leucovorin, and oxaliplatin); CapeOX (capecitabine and oxaliplatin); FOLFIRI (irinotecan, leucovorin, 5-FU); FOLFOXIRI (irinotecan, oxaliplatin, leucovorin, fluorouracil); IROX (oxaliplatin, irinotecan); oxaliplatin and irinotecan	Colorectal Cancer: Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Melanoma	45 mg PO BID, approximately 12 hours apart, in combination with Braftovi until disease progression or unacceptable toxicity	90 mg per day
Colon cancer, rectal cancer	45 mg PO BID with Braftovi and either Erbitux or Vectibix	90 mg per day

VI. Product Availability

Tablet: 15 mg

VII. References

1. Mektovi Prescribing Information. Boulder, CO: Array BioPharma Inc.; January 2019. Available at: <https://www.braftovimektovi.com/>. Accessed February 6, 2020.
2. National Comprehensive Cancer Network. Cutaneous Melanoma Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 6, 2020.
3. National Comprehensive Cancer Network. Colon Cancer Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed February 6, 2020.
4. National Comprehensive Cancer Network. Rectal Cancer Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed February 6, 2020.
5. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.24.18	08.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: added Medicaid line of business with 6/12 month initial/continued authorization duration; added NCCN compendium supported off-label use in colon and rectal cancers in combination with Braftovi and either Erbitux or Vectibix; references reviewed and updated.	02.06.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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