RXADVANCE
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Clinical Policy Title:	binimetinib
Policy Number:	RxA.226
Drug(s) Applied:	Mektovi®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Binimetinib (Mektovi®) is a kinase inhibitor. 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Binimetinib (Mektovi®)	Unresectable or metastatic melanoma	45 mg PO twice daily, approximately 12 hours apart, in combination with Braftovi until disease progression or unacceptable toxicity	90 mg per day
Binimetinib (Mektovi®)	Colon cancer, rectal cancer (off-label)	45 mg PO twice daily with Braftovi and either Erbitux or Vectibix	90 mg per day

Dosage Forms

- Tablet: 15 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Melanoma (must meet all)**:**

1. Diagnosis of melanoma with BRAF V600E or V600K mutation as:
   a. First-line therapy, in combination with encorafenib, for metastatic or unresectable disease or
   b. Second-line or subsequent therapy, in combination with encorafenib, for disease progression.

c. Adjuvant therapy, in combination with encorafenib, following complete resection of distant metastatic disease or in patients with unacceptable toxicities with dabrafenib/trametinib.

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with encorafenib (Braftovi™);
5. Dose does not exceed 90 mg (6 tablets) per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

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

1. Diagnosis of BRAF V600 E mutation positive colon cancer as:
   a. Primary treatment, in combination with cetuximab or panitumumab with encorafenib, for patients with metastatic disease and previous adjuvant FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months.
   b. Subsequent therapy, in combination with cetuximab or panitumumab with encorafenib, for progression of advanced or metastatic disease previously treated with any of the below:
      i. Oxaliplatin-based therapy without irinotecan
      ii. Irinotecan-based therapy without oxaliplatin
      iii. Oxalipatin and irinotecan
      iv. Fluoropyrimidine without irinotecan or oxaliplatin
      v. Fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or 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
Commercial: 6 months
Medicaid: 6 months

C. Rectal Cancer (off-label) (must meet all)**:**

1. Diagnosis of BRAF V600 E mutation positive rectal cancer as:
   a. Primary treatment, in combination with cetuximab or panitumumab with encorafenib, for patients with metastatic disease and previous adjuvant FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months.
   b. Subsequent therapy, in combination with cetuximab or panitumumab with encorafenib, for progression of advanced or metastatic disease previously treated with any of below:
      i. Oxaliplatin-based therapy without irinotecan
      ii. Irinotecan-based therapy without oxaliplatin
      iii. Oxalipatin and irinotecan
      iv. Fluoropyrimidine without irinotecan or oxaliplatin
      v. Fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab
2. Prescribed by or in consultation with an oncologist or hematologist;

3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or 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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All indications in section I (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance, 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, new dose does not exceed 90 mg (6 tablets) per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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 for all relevant lines of business and may require prior authorization.

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pembrolizumab, nivolumab, nivolumab/ipilimumab, dabrafenib/trametinib, vemuranib/cobimetinib	Unresectable or metastatic melanoma	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

- Contraindication(s):
  - None reported
- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
None

References

1. Mektovi Prescribing Information. Boulder, CO: Array Bio Pharma Inc; January 2019. Available at: https://www.braftovimektovi.com/. Accessed June 27, 2020.
2. National Comprehensive Cancer Network. Cutaneous Melanoma Version 3.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed June 27, 2020.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed June 27, 2020.
4. National Comprehensive Cancer Network. Rectal Cancer Version 6.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed June 27, 2020.
5. National Comprehensive Cancer Network. Colon Cancer Version 4.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed June 27, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Dosing information was updated to accompany updated indications. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. Appendix B was updated. 5. References were updated.	07/22/2020	09/14/2020