Clinical Policy Title:	binimetinib
Policy Number:	RxA.226
Drug(s) Applied:	Mektovi®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All line of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of unresectable or metastatic melanoma with BRAF V600E or V600K mutation;
2. Medication is prescribed in one of the following ways (a, b, c, or d):
   a. First-line therapy in combination with encorafenib;
   b. Second-line or subsequent therapy in combination with encorafenib, for disease progression if targeted therapy not previously used;
   c. Adjuvant therapy following unacceptable toxicities to dabrafenib/trametinib;
   d. Treatment of limited resectable disease and both of the following (i and ii):
      i. Prescbed as initial treatment in combination with encorafenib;
      ii. Member had unacceptable toxicities to dabrafenib/trametiniband one of the following (1 or 2):
         1) Stage III disease with clinical satellite/in-transit metastases;
         2) Local satellite/in-transit recurrence;
3. Prescribed in combination with encorafenib (Braftovi).

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Histiocytic Neoplasms (off-label) (must meet all)**:**

1. Diagnosis of Langerhans Cell Histiocytosis and one of the following (a, b, c, d, or e):
   a. Multisystem disease with symptomatic or impending organ dysfunction;
   b. Single-system lung disease;
   c. Multifocal single system bone disease not responsive to treatment with a bisphosphonate and >2 lesions;
   d. CNS lesions;
   e. Relapsed or refractory disease.
2. Member has a mitogen-activated protein kinase pathway mutation, or no detectable mutation, or testing not available.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Cutaneous Melanoma Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Histiocytic Neoplasms Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed August 28, 2024.

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. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. References were updated.	07/22/2020	09/14/2020
Policy was reviewed: 1. Policy title table was updated. 2. Colon cancer, rectal cancer (off-label) were removed from Initial Approval Criteria. 3. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 4. References were updated.	04/27/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, a. I.A.1: Updated indication criteria from Diagnosis of melanoma with BRAF V600E or V600K mutation as: to Diagnosis of unresectable or metastatic melanoma with BRAF V600E or V600K mutation as: 2. Continued Therapy Approval Crtieria, I.A.5: Updated Dosing criteria from If request is for a dose increase new dose does not exceed 90 mg per day to If request is for a dose increase, request meets one of the following (a or b) a. New dose does not exceed 90 mg 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).	01/19/2022	04/18/2022

Review/Revision History	Review/Revised Date	P&T Approval Date
*Prescribed regimen must be FDA-approved or recommended by NCCN. 3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Separated from I.A.1 to form a separate criteria. 2. Initial Approval Criteria, I.A.2.c: Updated Adjuvant therapy criteria from in combination with encorafenib, following complete resection of distant metastatic disease or in patients with unacceptable toxicities with dabrafenib/trametinib to Member has unacceptable toxicities to dabrafenib /trametinib or on the basis of agent side-effect profiles. 3. Initial Approval Criteria, I.A.2.d: Updated to include new disease criteria Member has limited resectable disease and meets all of the following (i and ii): i. Used as initial treatment in combination with encorafenib; ii. Member has unacceptable toxicities to dabrafenib/trametinib or on the basis of agent side effect profiles and one of the following (1 or 2): 1) Member has stage III disease with clinical satellite/in-transit metastases; 2) Member has local satellite/in-transit recurrence 4. Initial Approval Criteria, I.B: Updated to include approval criteria for Off label indication Histiocytic Neoplasms. 5. References were reviewed and updated.	12/27/2022	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy.	08/28/2024	9/13/2024

Review/Revision History	Review/Revised Date	P&T Approval Date
6. Updated approval duration verbiage. 7. References were reviewed and updated.		