MEDICATION POLICY:

BRAF/MEK Inhibitors

Generic Name: N/A

Therapeutic Class or Brand Name: BRAF/MEK Inhibitors

Applicable Drugs (if Therapeutic Class): Braftovi ® (Encorafenib), Mektovi® (Binimetinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/9/2019

Date Last Reviewed / Revised: 12/2/2023

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 through C AND must meet criteria listed under applicable diagnosis:

   A. Unresectable or metastatic melanoma

      1. Documentation of BRAF V600E or V600K mutations.
      2. Braftovi (encorafenib) will be used in combination with Mektovi (binimetinib).

   B. Unresectable, advanced, or metastatic colorectal cancer

      1. Documentation of BRAF V600E mutation.
      2. Documentation of intolerance to or progression after prior treatment.
      3. Braftovi (encorafenib) will be used in combination with Erbitux (cetuximab) or Vectibix (panitumumab).

   C. Metastatic non-small cell lung cancer (NSCLC)

      1. Documentation of BRAF V600E mutation.
      2. Braftovi (encorafenib) will be used in combination with Mektovi (binimetinib).

II. Minimum age requirement: 18 years old.

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 practice guidelines.

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, wild-type BRAF CRC, or wild-type BRAF NSCLC.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Braftovi
    - Melanoma: 180 capsules per 30 days
    - CRC: 120 capsules per 30 days
    - NSCLC: 180 capsules per 30 days.
- Mektovi: 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 the medication is effective.

APPENDIX

- N/A

REFERENCES

1. Braftovi. Prescribing information. Array BioPharma Inc; 2023 Accessed December 2, 2023. http://labeling.pfizer.com/ShowLabeling.aspx?id=12990 .
2. Mektovi. Prescribing information. Array BioPharma Inc; 2023. Accessed December 2, 2023. http://labeling.pfizer.com/ShowLabeling.aspx?id=12988 .
3. NCCN Clinical Practice Guidelines in Oncology. Cutaneous melanoma. V.3.2023. Updated October 27, 2023. Accessed December 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf .
4. NCCN Clinical Practice Guidelines in Oncology. Colon cancer. V.4.2023. Updated November16, 2023. Access December 2, 2023 https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf.
5. NCCN Clinical Practice Guidelines in Oncology. Rectal cancer. V.6.2023. Updated November 16, 2023. Accessed December 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf
6. NCCN Clinical Practice Guidelines in Oncology. Non small cell lung cancer. V.5.2023. Updated November 8, 2023. Accessed December 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

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.