

Clinical Pharmacy Program Guidelines for Mektovi

Program	Prior Authorization
Medication	Mektovi (binimetinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2018
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Mektovi™ (binimetinib) is a kinase inhibitor indicated, in combination with Braftovi™ (encorafenib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.

Information on FDA-approved tests for the detection of BRAF V600 mutations in melanoma may be found at: <http://www.fda.gov/CompanionDiagnostics>.¹

2. Coverage Criteria:

<p>A. <u>Melanoma</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Mektovi will be approved based on <u>all</u> of the following criteria:</p> <p>(1) <u>One</u> of the following diagnoses:</p> <p style="padding-left: 40px;">(a) Unresectable melanoma</p> <p style="padding-left: 40px;">(b) Metastatic melanoma</p> <p style="text-align: center;">-AND-</p> <p>(2) Patient is positive for BRAFV600 mutation</p>

-AND-

(3) Used in combination with Braftovi (encorafenib)

-AND-

(4) **One** of the following:

(a) Patient has a contraindication or history of intolerance to **one** of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

-OR-

(b) Provider attests that the patient is not an appropriate candidate for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

-OR-

(c) For continuation of prior Mektovi therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Mektovi** will be approved based on **both** of the following criteria:

(1) Patient does not show evidence of progressive disease while on Mektovi therapy

-AND-

(2) Used in combination with Braftovi (encorafenib)

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Mektovi** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Mektovi** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Mektovi therapy

Authorization will be issued for 12 months.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Mektovi [package insert]. Boulder, CO: Array BioPharma Inc.; January 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 12, 2020.

Program	Prior Authorization –Mektovi (binimetinib)
Change Control	
Date	Change
8/2018	New Program
1/2019	Added trial of alternative regimen prior to coverage for Braftovi/Mektovi. Updated references.
9/2019	Updated background and criteria to include NCCN recommended use in BRAF V600E colorectal cancer. Updated references.
6/2020	Updated background and criteria. Removed criteria for BRAFV600E colorectal cancer as no longer recommended by NCCN. Updated reference. Added Additional Clinical Rules Section.

