

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2021 P 1256-5
Program	Prior Authorization/Notification
Medication	Mektovi <sup>®</sup> (binimetinib)
P&T Approval Date	8/2018, 9/2019, 6/2020, 6/2021, 8/2021
Effective Date	11/1/2021; Oxford only: 11/1/2021

**1. Background:**

Mektovi<sup>®</sup> (binimetinib) is a kinase inhibitor indicated, in combination with Braftovi<sup>®</sup> (encorafenib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. The National Cancer Comprehensive Network (NCCN) guideline also recommends use of Mektovi in melanoma for *NRAS*-mutated tumors that have progressed after prior immune checkpoint inhibitor therapy.

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

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria:**

**A. Patients less than 19 years of age**

1. Mektovi will be approved based on the following criterion:

- a. Patient is less than 19 years of age

**Authorization will be issued for 12 months.**

**B. Melanoma**

1. **Initial Authorization**

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

(1) **All** of the following:

(a) **One** of the following diagnoses:

- i. Unresectable melanoma
- ii. Metastatic melanoma

**-AND-**

(b) Patient is positive for BRAFV600 mutation

**-AND-**

(c) Used in combination with Braftovi (encorafenib)

**-OR-**

(2) **Both** of the following:

(a) Diagnosis of melanoma *NRAS*-mutated tumor

**-AND-**

(b) Progression after prior immune checkpoint inhibitor 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) **One** of the following:

(a) **Both** of the following:

- i. BRAFV600 mutation positive
- ii. Used in combination with Braftovi (encorafenib)

**-OR-**

(b) *NRAS*-mutated tumor

**Authorization will be issued for 12 months.**

**C. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**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.; October 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [www.nccn.org](http://www.nccn.org). Accessed April 27, 2021.

Program	Prior Authorization/Notification - Mektovi (binimetinib)
<b>Change Control</b>	
8/2018	New program
9/2019	Annual review. Updated background and criteria to include NCCN recommended use in BRAF V600 E colorectal cancer. Updated references. Added general NCCN recommended review criteria.
6/2020	Updated background and criteria. Removed criteria for BRAFV600E colorectal cancer as no longer recommended by NCCN.
6/2021	Annual review. Added criteria in melanoma for <i>NRAS</i> -mutated tumors. Updated reference.
8/2021	Updated reauthorization criteria to not require Braftovi combination therapy for <i>NRAS</i> -mutated tumor.