UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1256-8
Program	Prior Authorization/Notification
Medication	Mektovi® (binimetinib)
P&T Approval Date	8/2018, 9/2019, 6/2020, 6/2021, 8/2021, 8/2022, 8/2023, 12/2023
Effective Date	3/1/2024

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 and for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E 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, multisystem, single-system, or CNS lesion Langerhans Cell Histiocytosis with a mitogen-activated protein (MAP) kinase pathway mutation, low-grade serous carcinoma, and in combination with imatinib (Gleevec) for succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors (GIST) with gross residual disease (R2 resection), unresectable primary disease, tumor rupture or recurrent/metastatic disease.

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

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]:

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:

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(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

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Authorization will be issued for 12 months.

C. Histiocytic Neoplasms

1. **Initial Authorization**

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

      (1) Diagnosis of **one** of the following:

         (a) Multisystem Langerhans Cell Histiocytosis
         (b) Single-system lung Langerhans Cell Histiocytosis
         (c) Langerhans Cell Histiocytosis with CNS lesions

      -AND-

      (2) Disease is positive for mitogen-activated protein (MAP) kinase pathway mutation, or no detectable mutation, or testing not available

      Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

      Authorization will be issued for 12 months.

D. Serous Carcinoma

1. **Initial Authorization**

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

      (1) Diagnosis of low-grade serous carcinoma

      -AND-

      (2) Disease is recurrent

      Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

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Authorization will be issued for 12 months.

E. Gastrointestinal Stromal Tumor (GIST)

1. **Initial Authorization**

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

      (1) Diagnosis of succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor (GIST)

      -AND-

      (2) Disease is **one** of the following:

         (a) Gross residual disease (R2 resection)
         (b) Unresectable primary disease
         (c) Tumor rupture
         (d) Progressive
         (e) Recurrent
         (f) Metastatic

      -AND-

      (3) Used in combination with imatinib mesylate (Gleevec)

      Authorization will be issued for 12 months.

2. **Reauthorization**

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

      (1) Patient does not show evidence of progressive disease while on **Mektov**i therapy

      Authorization will be issued for 12 months.

F. Non-Small Cell Lung Cancer

1. **Initial Authorization**

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

      (1) Diagnosis of non-small cell lung cancer (NSCLC)

      -AND-

      (2) Disease is metastatic

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-AND-

(3) Patient is positive for BRAFV600 mutation

-AND-

(4) Used in combination with Braftovi (encorafenib)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

Authorization will be issued for 12 months.

G. 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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 16, 2023.

Program	Prior Authorization/Notification - Mektovi (binimetinib)
Change Control	
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

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	colorectal cancer as no longer recommended by NCCN.
6/2021	Annual review. Added criteria in melanoma for *NRAS*-mutated tumors. Updated reference.
8/2021	Updated reauthorization criteria to not require Braftovi combination therapy for *NRAS*-mutated tumor.
8/2022	Annual review. Updated background and reference. Added criteria per NCCN recommendations for histiocytic neoplasms and serous carcinoma. Added state mandate footnote.
8/2023	Annual review. Added criteria per NCCN recommendations for SDH-deficient GIST. Updated background and reference.
12/2023	Updated background and criteria to include new FDA approved use in BRAF V600E NSCLC. Updated references.

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