UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3117-9
Program	Step Therapy
Medication	Braftovi® (encorafenib)
P&T Approval Date	1/2019, 2/2020, 2/2021, 2/2022, 4/2022, 4/2023, 8/2023, 8/2024, 8/2025
Effective Date	11/1/2025

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one BRAF inhibitor/MEK inhibitor combination regimen before providing coverage for Braftovi/Mektovi for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, and for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation.

Braftovi (encorafenib) and Mektovi (binimetinib) are indicated in combination for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, and for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation.

Tafinlar (dabrafenib) and Mekinist (trametinib) are indicated in combination for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, and for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation.

Zelboraf (vemurafenib) and Cotellic (cobimetinib) are indicated in combination for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.

Members currently on Braftovi and Mektovi therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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,b]:

A. <u>Patients less than 19 years of age</u>

1. **Braftovi** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Melanoma</u>

1. **Braftovi** will be approved based on **<u>both</u>** of the following criteria:

   a. Braftovi is to be used in combination with Mektovi (binimetinib)

   -AND-

   b. **<u>One</u>** of the following:

      (1) Patient has a contraindication or history of intolerance, to **<u>one</u>** of the following regimens:

         (a) Tafinlar (dabrafenib) plus Mekinist (trametinib)

         (b) Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

      -OR-

      (2) Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for either of the following regimens:

         (a) Tafinlar (dabrafenib) plus Mekinist (trametinib)

         (b) Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

      -OR-

      (3) **<u>Both</u>** of the following:

         (a) As continuation of therapy

         -AND-

         (b) Patient has **<u>not</u>** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Pfizer Oncology Together sponsored Co-Pay Savings Program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Braftovi.

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer Oncology Together sponsored Co-Pay Savings Program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. Non-Small Cell Lung Cancer

1. **Braftovi** will be approved based on **both** of the following criteria:

   a. Braftovi is to be used in combination with Mektovi (binimetinib)

   -AND-

   b. **One** of the following:

      (1) Patient has a contraindication or history of intolerance to Tafinlar (dabrafenib) plus Mekinist (trametinib)

      -OR-

      (2) Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for Tafinlar (dabrafenib) plus Mekinist (trametinib)

      -OR-

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

         (a) As continuation of therapy

         -AND-

         (b) Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Pfizer Oncology Together sponsored Co-Pay Savings Program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Braftovi.

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer Oncology Together sponsored Co-Pay Savings Program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

D. Other Indications

1. **Braftovi** will be approved

   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.
[b] Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Braftovi [package insert]. Boulder, CO: Array BioPharma Inc.; October 2023.
2. Mektovi [package insert]. Boulder, CO: Array BioPharma Inc.; October 2023.
3. Zelboraf [package insert]. South San Francisco, CA: Genentech, Inc.; May 2020.
4. Cotellic [package insert]. Genentech USA, Inc.: South San Francisco, CA; May 2023.
5. Tafinlar [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2025.
6. Mekinist [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2025.
7. The NCCN Drugs and Biologics Compendium® (NCCN Compendium). Available at https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed July 2, 2025.

Program	Step Therapy – Braftovi (encorafenib)
Change Control	
1/2019	New program.
2/2020	Annual review with no changes to clinical coverage criteria. Updated references.
2/2021	Annual review with no changes to clinical coverage criteria. Updated references and manufacturer co-pay savings program name.
2/2022	Annual review with no changes to clinical coverage criteria. Updated references.
4/2022	Updated oncology medications state mandate note.
4/2023	Annual review with no changes to clinical criteria. Updated references.
8/2023	Updated wording of provider attestation that the patient is not an appropriate candidate for the required alternatives.

8/2024	Annual review. Added non-small cell lung cancer section, updated background with new indications. Updated references.
8/2025	Annual review. No changes to coverage criteria. Updated references.