



PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – BRAF Inhibitor) – Braftovi Prior Authorization Policy

- Braftovi® (encorafenib capsules – Array)

REVIEW DATE: 08/20/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Braftovi, a BRAF inhibitor, is indicated for the following:¹

- **Colorectal cancer**, in combination with Erbitux® (cetuximab intravenous infusion) and mFOLFOX6 (5-FU, leucovorin, and oxaliplatin), for the treatment of metastatic disease with a *BRAF V600E* mutation, as detected by an FDA-approved test.
- **Colorectal cancer**, in combination with Erbitux, for the treatment of metastatic disease with a *BRAF V600E* mutation, as detected by an FDA-approved test, after prior therapy in adults.
- **Melanoma**, in combination with Mektovi® (binimetinib tablets), for the treatment of unresectable or metastatic disease with a *BRAF V600E* or *V600K* mutation, as detected by an FDA-approved test.
- **Non-small cell lung cancer (NSCLC)**, in combination with Mektovi, for the treatment of metastatic NSCLC with a *BRAF V600E* mutation, as detected by an FDA-approved test in adults.

The indication for Braftovi in colorectal cancer in the first-line setting is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Limitation of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF colorectal cancer, or wild-type BRAF NSCLC.

Guidelines

Braftovi is discussed in guidelines from the National Comprehensive Cancer Network (NCCN).⁵

- **Colon and Rectal Cancer:** NCCN guidelines for colon cancer (version 4.2025 – June 27, 2025) and rectal cancer (version 2.2025 – March 31, 2025) recommend Braftovi for some situations in patients with *BRAF V600E*-mutated disease.³ Braftovi + Erbitux or Vectibix[®] (panitumumab intravenous infusion) + FOLFOX is recommended as initial therapy for advanced or metastatic *BRAF V600E* mutation-positive disease (category 2A). For second-line or subsequent disease, Braftovi + Erbitux or Vectibix (category 2A) or Braftovi + Erbitux or Vectibix + FOLFOX (category 2B) is recommended. For primary treatment (following adjuvant chemotherapy) or as subsequent use, Braftovi + Erbitux or Vectibix[®] (panitumumab intravenous infusion) is a recommended treatment option for *BRAF V600E* mutation-positive disease (category 2A). NCCN Compendium recommends the use of Braftovi for appendiceal adenocarcinoma for *BRAF V600E* mutation-positive advanced or metastatic disease in combination with Erbitux or Vectibix.⁵
- **Melanoma, Cutaneous:** NCCN guidelines (version 2.2025 – January 28, 2025) recommend BRAF/MEK inhibitor combinations among the “Preferred” therapies for first-line (category 1) and subsequent treatment (category 2A) of metastatic or unresectable melanoma with a *BRAF V600*-activating mutation.² The combinations are also recommended for adjuvant treatment (category 2B). While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor (Tafinlar[®] [dabrafenib capsules] or Zelboraf[®] [vemurafenib tablets]) is a recommended option, especially in patients who are not appropriate candidates for checkpoint immunotherapy.
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 7.2025 – July 10, 2025) recommend Braftovi + Mektovi and Tafinlar + Mekinist[®] (trametinib tablets) combinations for first-line “Preferred” regimens and as subsequent therapies (both category 2A) for *BRAF V600E* mutation-positive recurrent, advanced, or metastatic disease.⁶ Zelboraf or Tafinlar monotherapy is also recommended under “Useful in Certain Circumstances” (both category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Braftovi. All approvals are provided for the duration noted below.

- **Braftovi® (encorafenib capsules - Array)**
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

- 1. Colon or Rectal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A)** Patient is \geq 18 years of age; AND
 - B)** Patient has *BRAF V600E* mutation-positive disease; AND
 - C)** Patient meets ONE of the following (i or ii):
 - i.** Patient meets ALL of the following (a, b, and c):
 - a)** The medication will be used as first-line systemic therapy for metastatic disease; AND
 - b)** The medication will be used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion); AND
 - c)** The medication will be used in combination with FOLFOX (5-FU, leucovorin, and oxaliplatin); OR
 - ii.** Patient meets BOTH of the following (a and b):
 - a)** Patient has previously received a chemotherapy regimen for colon or rectal cancer; AND
Note: Examples of chemotherapy regimens include a fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine; oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin).
 - b)** The medication is used in combination with Erbitux or Vectibix.
- 2. Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A)** Patient is \geq 18 years of age; AND
 - B)** Patient has unresectable, advanced, or metastatic melanoma; AND
 - C)** Patient has *BRAF V600* mutation-positive disease.
- 3. Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A)** Patient is \geq 18 years of age; AND
 - B)** Patient has recurrent, advanced, or metastatic disease; AND
 - C)** Patient has *BRAF V600E* mutation-positive disease; AND
 - D)** The medication will be taken in combination with Mektovi (binimetinib tablets).

Other Uses with Supportive Evidence

- 4. Appendiceal Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A)** Patient is \geq 18 years of age; AND
 - B)** Patient has *BRAF V600E* mutation-positive disease; AND

- C)** Patient has advanced or metastatic disease; AND
D) The medication will be used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).

CONDITIONS NOT COVERED

- **Braftovi® (encorafenib capsules - Array) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

REFERENCES

1. Braftovi® capsules [prescribing information]. Boulder, CO: Array BioPharma; December 2024.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 14, 2025.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – June 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 14, 2025.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 14, 2025.
5. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 14, 2025. Search terms: encorafenib.
6. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2025 – July 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 14, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	07/19/2023
Selected Revision	Non-Small Cell Lung Cancer: Added new FDA-approved indication and criteria	10/18/2023
Annual Revision	Appendiceal Adenocarcinoma: Added new approval condition and criteria under “Other Uses with Supportive Evidence” based on compendium/guideline recommendations.	8/14/2024
Selected Revision	Colon or Rectal Cancer: Added new criterion for Braftovi use in combination with Erbitux and mFOLFOX6 for first-line therapy based on FDA approval. Also, for subsequent therapy use, modified criteria which referred to combination therapy of Braftovi to be more specific. Now the criterion states Braftovi in used in “combination with Erbitux or Vectibix (panitumumab intravenous infusion).” Deleted Note that provided examples of combination therapies.	01/29/2025
Update	04/08/2025: The policy name was changed from “Oncology – Braftovi PA Policy” to “Oncology (Oral - BRAF Inhibitor) – Braftovi PA Policy”.	N/A
Annual Revision	Colon or Rectal Cancer: Vectibix was added and “mFOLFOX6” was updated to “FOLFOX” in the following requirement which now states, “the medication will be used in combination with Erbitux (cetuximab	08/20/2025

	<p>intravenous infusion) or Vectibix (panitumumab intravenous infusion) and FOLFOX (5-FU, leucovorin, and oxaliplatin)."</p> <p>Non-Small Cell Lung Cancer: An option for approval was added if the patient has recurrent or advanced disease.</p> <p>Appendiceal Adenocarcinoma: The requirement that the "medication will be used as subsequent therapy" was removed.</p>	
--	---	--

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.