

Braftovi

Bahrain · access guide

How to access Braftovi and Mektovi or cetuximab for BRAF V600E and V600K mutant melanoma, BRAF V600E mutant metastatic colorectal cancer, and BRAF V600E mutant non-small cell lung cancer from Bahrain: 2026 pathway via Bahrain medical oncology, molecular diagnostics, and pharmacy supply

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Bahrain has a focused adult oncology footprint. Salmaniya Medical Complex (SMC) medical oncology, King Hamad University Hospital (KHUH) oncology, Bahrain Defence Force (BDF) Hospital oncology, Bahrain Oncology Center, and Bahrain Specialist Hospital oncology treat BRAF-mutant melanoma, metastatic colorectal cancer, and metastatic non-small cell lung cancer through molecular diagnostics, MDT review, and combination-therapy regimens. Braftovi (encorafenib, Pfizer) is the oral BRAF V600E and V600K inhibitor. It is almost always given in combination, never as monotherapy: with binimetinib (Mektovi) for melanoma and NSCLC, and with cetuximab (Erbix) for colorectal cancer. For a Bahrain-resident adult with confirmed BRAF V600E or V600K mutation in one of these three cancers, the operational question is which combination regimen fits the indication, how the two drugs are pre-authorized together, whether the prescription is dispensed in-country or via cross-border supply, and how insurance and out-of-pocket exposure work over a 9 to 18 month treatment course. For complex cases, cross-border referral to KFSHRC Riyadh or NCCCR Doha is an established pattern. Sidra Medicine is paediatric only and is not in scope for any Braftovi indication.

The NHRA regulatory framework governs the registration pathway for oncology drugs. Adult only across all three indications.

Reserve Meds does not promote one BRAF inhibitor over another.

Why Braftovi and Mektovi or cetuximab and why now

Encorafenib is an ATP-competitive small-molecule inhibitor of mutant BRAF V600E and V600K kinase. Its pharmacology distinguishes it from earlier BRAF inhibitors (vemurafenib, dabrafenib) through a longer dissociation half-life from the kinase target, producing more sustained MAPK pathway inhibition. The combination partner is indication-specific: binimetinib (Mektovi) for melanoma and NSCLC, cetuximab for colorectal cancer. The COLUMBUS trial (melanoma) showed median overall survival of 33.6 months on Braftovi plus Mektovi versus 16.9 months on vemurafenib. The BEACON CRC trial showed median overall survival of 9.3 months for the Braftovi plus cetuximab doublet versus 5.9 months for standard-of-care in BRAF V600E mutant metastatic colorectal cancer. The PHAROS trial (NSCLC) showed a 75 percent objective response rate in treatment-naïve BRAF V600E mutant NSCLC.

FDA approved June 2018 (melanoma, with binimetinib), April 2020 (colorectal cancer, with cetuximab), October 2023 (NSCLC, with binimetinib). EMA approvals followed on parallel timelines. The October 2023 NSCLC indication is recent enough that in mid-2026 the Bahrain NHRA label may not yet reflect that scope.

What Braftovi is, in plain language

Oral capsule. Taken once daily with food. No infusion of Braftovi itself. Six 75 mg capsules (450 mg total) for melanoma and NSCLC; four 75 mg capsules (300 mg total) for colorectal cancer. Storage at room temperature. Refill on a 30-day cycle.

The combination partner depends on the indication. For melanoma and NSCLC, Mektovi (binimetinib) is two 15 mg tablets twice daily (45 mg dose, four tablets per day total). Mektovi is also oral, also home-administered. For colorectal cancer, cetuximab is an IV infusion at the prescribing centre's infusion unit on a weekly schedule (60 to 120 minute IV). The patient receiving Braftovi for CRC keeps a weekly clinic appointment for cetuximab while taking Braftovi at home daily.

Eligibility at a Bahrain oncologist's clinic

1. Histologically confirmed cutaneous melanoma, metastatic colorectal adenocarcinoma, or metastatic non-small cell lung cancer (predominantly adenocarcinoma).
2. Confirmed BRAF V600E or V600K mutation by NGS, PCR (cobas BRAF V600 assay), or VE1 immunohistochemistry. NGS is preferred and is performed at the centre's pathology laboratory or sent to KFSHRC molecular pathology, NCCCR molecular pathology, or international reference labs (Caris, Foundation Medicine). Turnaround 2 to 4 weeks for NGS; 3 to 10 days for PCR or IHC.
3. For metastatic colorectal cancer, documented RAS status (KRAS, NRAS wild-type) before cetuximab partner can be authorised.
4. Adult (18+).
5. Staging workup appropriate to indication: contrast CT chest, abdomen, pelvis; brain MRI (all three indications carry meaningful CNS-metastasis risk).
6. Baseline complete blood count, comprehensive metabolic panel including LFTs, fasting glucose, lipid panel.
7. Baseline ECG with QTc documentation.
8. Baseline ophthalmologic exam (slit-lamp and dilated funduscopy); uveitis is a class effect of BRAF plus MEK combinations.
9. Baseline echocardiogram with LVEF documentation; Mektovi can reduce left ventricular function.
10. Baseline dermatology review; keratoacanthomas and cutaneous squamous cell carcinomas are a recognised class effect of BRAF inhibitors.
11. Pregnancy and lactation screen. Effective contraception required for women of reproductive potential.
12. Drug interaction screen for CYP3A4 inhibitors and inducers; avoid grapefruit.

The Bahrain prescribing and supply picture, plainly

Braftovi availability in Bahrain depends on NHRA registration status at the point of prescription. The melanoma indication has the longest registration history and runs through standard commercial supply. The colorectal cancer indication and particularly the October 2023 NSCLC indication may require named-patient cross-border supply from KSA or UAE distributors where the local NHRA label has not yet caught up.

1. **Prescribing physician:** board-certified Bahraini medical oncologist; subspecialty by indication (cutaneous oncology for melanoma, GI oncology for colorectal cancer, thoracic oncology for NSCLC). Major services: SMC oncology, KHUH oncology, BDF Hospital oncology, Bahrain Oncology Center, Bahrain Specialist Hospital oncology. 2. **Molecular diagnostics:** BRAF V600 testing at the prescribing centre's pathology lab, at KFSHRC or NCCCR molecular pathology, or sent to international reference lab. RAS status for CRC patients in the same workup. 3. **MDT review:** melanoma, GI, or thoracic tumour board reviews each BRAF V600 positive case before initiating Braftovi plus combination partner. Documents combination rationale and partner choice. 4. **Pharmacy dispensing:** hospital pharmacy or partnered specialty pharmacy fills Braftovi and Mektovi together (melanoma, NSCLC) on a 30-day refill cycle. Cetuximab (CRC) is administered at the centre's infusion unit weekly. 5. **Cross-border supply:** where Bahrain NHRA scope does not yet cover the indication, named-patient cross-border supply runs from Saudi (KFSHRC) or UAE distributors via Pfizer's regional access channel. For complex multidisciplinary cases (CNS-predominant melanoma, BRAF-mutant CRC with peritoneal disease, BRAF-mutant NSCLC with advanced staging), cross-border referral to KFSHRC Riyadh or NCCCR Doha is an established Bahraini pattern. 6. **Insurance and MoH coverage:** for Bahraini nationals, MoH cover for advanced oncology drugs on a case-by-case basis. Commercial cover (AXA Gulf, Bahrain National Insurance, GIG Bahrain, regional Bupa product) varies. Pre-authorisation conversation is always two drugs in parallel. [VERIFY: current NHRA registration status across melanoma, CRC, and NSCLC indications at intake.]`

The 2026 pathway, step by step

Week 0 to 1: Documentation pack with the treating medical oncologist's office. BRAF V600 testing requisition if not yet performed. RAS testing requisition for CRC patients.

Week 1 to 4: Molecular results returned. MDT review and combination-partner rationale documented.

Week 2 to 5: Insurance pre-authorisation for Braftovi plus Mektovi (melanoma, NSCLC) or Braftovi plus cetuximab (CRC) in parallel. NHRA registration scope confirmed; cross-border named-patient pathway initiated if required.

Week 4 to 7: First dispense. Baseline labs, ECG, echocardiogram, ophthalmology, dermatology completed. First Braftovi capsules and Mektovi tablets dispensed (melanoma, NSCLC) or first cetuximab infusion at the centre plus Braftovi take-home supply (CRC).

Ongoing: Daily oral Braftovi (and Mektovi) at home, refilled monthly. Weekly cetuximab infusion at the centre for CRC patients.

Month 1 to 6: LFTs every 2 weeks, CBC every 2 to 4 weeks, ECG at 2 weeks and 1 month, LVEF at 1 month, ophthalmology at 1 month, dermatology every 8 weeks. Imaging response assessment at 8 to 12 weeks.

Month 6 onwards: LFTs and CBC monthly, LVEF every 2 to 3 months, ophthalmology every 6 months or symptom-driven, dermatology every 8 weeks. Imaging every 8 to 12 weeks. Treatment continues until disease progression or intolerable toxicity.

Cost expectation in BHD

US list price for Braftovi alone approximately USD 12,000 to 15,000 per 30-day supply at the 450 mg dose (melanoma, NSCLC); USD 8,000 to 11,000 at the 300 mg dose (CRC). Combined Braftovi plus Mektovi regimen approximately USD 25,000 to 30,000 per month. Combined Braftovi plus cetuximab regimen approximately USD 25,000 to 35,000 per month depending on patient body surface area.

At 2026 indicative cross rates, the BHD-equivalent monthly combined-regimen cost band is approximately BHD 9,400 to 13,200 at list price. Annual combined-regimen cost band approximately BHD 113,000 to 158,000 at list price. Median treatment duration is approximately 14 to 18 months for melanoma, 9 to 12 months for colorectal cancer, and 9 to 15 months for NSCLC.

For Bahraini nationals, MoH cover for advanced oncology drugs on a case-by-case basis. Commercial cover varies and typically requires biomarker confirmation plus MDT rationale documented in the file. Pfizer regional access programmes may underwrite portions of the cost for specific cohorts; Mektovi and cetuximab partners have separate access programme channels.

What to monitor

The combination regimens carry several recognised signals that the prescribing centre and the patient track together.

Liver function: AST and ALT every 2 weeks for the first 6 months, then monthly. Grade 3 or higher elevations require dose interruption per protocol.

Cardiac function: baseline LVEF, then every 2 to 3 months on the Mektovi-containing combinations (melanoma, NSCLC). Mektovi can reduce left ventricular function; a new LVEF reduction warrants dose interruption.

QT interval: baseline ECG, then at 2 weeks and 1 month, then as clinically indicated. Symptomatic QT prolongation is uncommon but recognised.

Ophthalmology: any new visual symptom (blurred vision, photopsia, scotoma) prompts urgent ophthalmology review for uveitis or serous retinopathy. Routine review at 1 month, then every 6 months.

Skin: dermatology surveillance every 8 weeks for keratoacanthomas and cutaneous squamous cell carcinomas. The signal is less prominent on Braftovi than on monotherapy BRAF inhibitors but is real.

For cetuximab partner (CRC): infusion reactions on first infusion, hypomagnesaemia requiring electrolyte replacement, acneiform rash that is class-typical and managed with topical or oral antibiotic regimens.

Pyrexia: less prominent on Braftovi plus Mektovi than on dabrafenib plus trametinib but still recognised.

Religious, ethical, and family-logistics framing

Braftovi and Mektovi are oral small molecules with no animal-source content that creates a halal concern. Cetuximab is a chimeric monoclonal antibody produced in SP2/0 mouse myeloma cells; the classical Islamic jurisprudential framework for life-threatening illness already endorses monoclonal antibody therapy. Bahraini Islamic medical ethics treats oncology drug therapy as standard chronic medication.

The combination structure is the central practical point. For melanoma and NSCLC, the patient takes six Braftovi capsules once daily plus two Mektovi tablets twice daily at home. The pill burden is meaningful and the adherence routine (medication diary, pill organiser, smartphone reminders, family co-monitoring) is set up at the first dispense. For colorectal cancer, the patient's week is anchored by the weekly cetuximab infusion at the centre plus daily oral Braftovi at home.

Skin surveillance every 8 weeks during treatment is a practical commitment that the Bahraini UV-intense climate adds salience to. The prescribing centre's dermatology service is looped in early.

The two-drug financial conversation is heavier than for most other Reserve Meds catalogue drugs. The combined regimen at USD 25,000 to 40,000-plus per month, on an indefinite-duration treatment course, is a major family financial reality. The centre's pre-authorisation review for both drugs together is the gating step before the first dispense.

When Braftovi is not the right call

BRAF V600 wild-type cancer (Braftovi is biomarker-gated and not appropriate), severe baseline cardiac dysfunction (LVEF below local protocol threshold), active uveitis, severe baseline liver dysfunction, untreated CNS metastases with active neurological symptoms (requires CNS-directed treatment first in most cases), pregnancy without effective contraception, and severe drug-drug interaction profile (strong CYP3A4 inhibitors or inducers that cannot be substituted):

- For BRAF V600 mutant melanoma: dabrafenib plus trametinib or vemurafenib plus cobimetinib are alternative BRAF plus MEK combinations with different tolerability profiles; immune checkpoint inhibitors are a parallel first-line option regardless of BRAF status. - For BRAF V600E mutant metastatic colorectal cancer: standard chemotherapy regimens (FOLFOX, FOLFIRI plus cetuximab or bevacizumab) for the prior-line setting; the original BEACON triplet (encorafenib plus binimetinib plus cetuximab) remains a reference at some centres. - For BRAF V600E mutant metastatic NSCLC: dabrafenib plus trametinib as the older BRAF plus MEK combination; immune checkpoint inhibitor plus chemotherapy regimens appropriate to stage and biomarker profile.

Reserve Meds does not promote one BRAF inhibitor over another.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Bahraini Braftovi case we build the documentation pack with the treating medical oncologist's office, confirm NHRA registration status across the relevant indication (melanoma, CRC, NSCLC) and the appropriate dispensing pathway (in-country versus cross-border named-patient from KSA or UAE), run the two-drug insurance pre-authorisation in parallel with the clinical pre-authorisation, coordinate the supply logistics for both the Braftovi component and the combination partner (Mektovi or cetuximab), align the cross-border referral to KFSHRC Riyadh or NCCCR Doha if the case is complex, and stay with the case through the first year of dosing. Clinical decisions remain with your treating medical oncologist.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

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