Cotellic

Saudi Arabia · access guide

How to access Cotellic (with Zelboraf and optionally Tecentriq) for BRAF V600E/V600K metastatic melanoma from Saudi Arabia: 2026 pathway via medical oncology and combination supply | Reserve Meds

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

Saudi Arabia holds the deepest adult medical oncology capability in the Gulf, anchored by King Faisal Specialist Hospital and Research Centre (KFSHRC) in Riyadh and Jeddah, King Abdulaziz Medical City (KAMC) under the National Guard Health Affairs, King Fahad Medical City (KFMC) Riyadh, King Fahad Hospital Dammam, and King Abdulaziz University Hospital (KAUH) Jeddah. Each of these centres runs a medical oncology service with active BRAF V600 molecular testing through onsite NGS and reference-laboratory partnerships, dermato-oncology and melanoma subspecialty review, and standing payer pre-authorisation experience for BRAF/MEK combination regimens. Cotellic (cobimetinib) is the Genentech / Roche oral MEK1/2 inhibitor that is approved by the FDA only in combination with vemurafenib (Zelboraf), with or without atezolizumab (Tecentriq), for BRAF V600E or V600K unresectable or metastatic melanoma. A Cotellic case in Saudi Arabia is always a two-drug or three-drug case, and the payer conversation is always a combination conversation. Reserve Meds does not promote one BRAF/MEK combination over another; the page below describes the Cotellic combination because that is what the patient or family is asking about.

This page explains how the pathway works in 2026 for a Saudi-resident adult: who qualifies, where the molecular diagnostics, baseline ophthalmologic exam, baseline echocardiogram, and baseline liver and creatine kinase workup happen, where the prescriptions for Cotellic AND Zelboraf are written and filled together, what the realistic out-of-pocket exposure band is in SAR for the combined regimen, what to monitor on therapy (retinal serous changes, photosensitivity, LVEF, LFTs, CK), and how a multi-month combination course settles into a Saudi family's life.

Why Cotellic, and why now

Cotellic is cobimetinib, an oral, highly selective, reversible inhibitor of mitogen-activated protein kinase kinase 1 and 2 (MEK1 and MEK2). It was discovered at Exelixis and developed and brought to FDA approval in November 2015 by Genentech (Roche Group). The pharmacological logic is the MAPK cascade: BRAF V600E or V600K mutation produces a constitutively active mutant BRAF kinase that drives MEK and then ERK, sustaining tumour growth and survival independently of normal upstream RAS regulation. Adding a MEK inhibitor downstream of BRAF blocks the paradoxical pathway activation in BRAF wild-type cells that drives the keratoacanthoma and cutaneous squamous cell carcinoma signal of BRAF monotherapy, and improves overall survival relative to BRAF monotherapy.

The two pivotal FDA approvals for Cotellic in melanoma are the November 2015 doublet approval based on the coBRIM trial (NEJM 2014, updated Lancet Oncology 2016) and the July 2020 triplet approval based on the IMspire150 trial (Lancet 2020):

- **coBRIM doublet (Cotellic 60 mg QD oral, 21 days on / 7 days off, plus Zelboraf 960 mg BID continuous)**: median progression-free survival 12.3 months on the doublet versus 7.2 months on Zelboraf monotherapy; median overall survival 22.3 months versus 17.4 months. - **IMspire150 triplet (Cotellic plus Zelboraf plus atezolizumab)**: median PFS 15.1 months on the triplet versus 10.6 months on the doublet placebo arm. The triplet is the first-line option that adds a PD-L1 checkpoint inhibitor (atezolizumab, Tecentriq) to the BRAF/MEK backbone.

In October 2022 Cotellic received an expanded approval for histiocytic neoplasms (Erdheim-Chester disease, Langerhans cell histiocytosis, Rosai-Dorfman disease) at the 60 mg QD continuous schedule. The Saudi melanoma practice in 2026 is the main use case and is the focus of this page.

For a Saudi patient with confirmed BRAF V600E or V600K-mutant unresectable or metastatic melanoma, the Cotellic plus Zelboraf doublet sits as one of three FDA-approved BRAF/MEK doublets (alongside dabrafenib plus trametinib, Tafinlar plus Mekinist; and encorafenib plus binimetinib, Braftovi plus Mektovi). The triplet adds Tecentriq for selected first-line patients. Reserve Meds does not promote one BRAF/MEK combination over another.

What Cotellic is, in plain language

Cotellic is an oral 20 mg tablet. The standard dose is three tablets (60 mg) once daily for 21 consecutive days, followed by 7 days off, repeated every 28 days. Taken with or without food. The companion drug Zelboraf is an oral 240 mg tablet taken as four tablets (960 mg) twice daily, continuously without scheduled breaks. Both drugs are dispensed from the prescribing centre's oncology pharmacy or partnered specialty pharmacy on a 28-day refill cycle synchronised to the Cotellic cycle. If atezolizumab (Tecentriq) is added (IMspire150 triplet first-line), the patient also visits the infusion suite for IV Tecentriq on the protocol schedule.

There is no infusion of Cotellic itself and no infusion of Zelboraf. The treatment is oral and outpatient. The patient comes to the prescribing centre for monitoring labs, ophthalmologic surveillance, and echocardiogram on the schedule below.

Eligibility at a Saudi medical oncologist's clinic

For Saudi-resident patients, the medical oncology service applies the FDA, EMA, SFDA, and major-guideline criteria:

1. Histologically confirmed unresectable or metastatic cutaneous melanoma. 2. Confirmed BRAF V600E or V600K mutation by NGS, PCR (cobas BRAF V600 Mutation Test or equivalent), or IHC with VE1 antibody confirmed by molecular method. 3. Adult patient (18 or older). The melanoma indication is adult. 4. Staging workup with contrast CT, PET-CT where indicated, and brain MRI for CNS staging. 5. Baseline ophthalmologic examination including slit-lamp, dilated funduscopic exam, and optical coherence tomography (OCT). Serous retinopathy and retinal vein occlusion are recognised Cotellic class effects and prescribing without baseline ophthalmologic clearance is not appropriate. 6. Baseline echocardiogram with documented left ventricular ejection fraction (LVEF). Cotellic can cause cardiomyopathy with reduced LVEF and prescribing without baseline echo is not appropriate. 7. Baseline laboratory workup including LFTs (AST, ALT, bilirubin, alkaline phosphatase), creatine kinase (CK), CBC, comprehensive metabolic panel, fasting glucose, lipid panel, and pregnancy test where relevant. 8. Drug interaction screen. Cobimetinib is metabolised by CYP3A4; strong inhibitors (clarithromycin, ketoconazole, ritonavir) and strong inducers (rifampin, phenytoin, carbamazepine, St John's wort) modify exposure substantially. 9. Photosensitivity counsel. Cotellic plus Zelboraf carries a severe photosensitivity signal that is distinctive within the BRAF/MEK combination class. Strict sun avoidance, broad-spectrum SPF 50+, protective clothing, and avoidance of midday outdoor exposure are mandatory for the entire treatment course. The Saudi UV-intense climate makes this counselling load operationally significant. 10. Pregnancy and contraception planning. Effective contraception is required during treatment and for at least 2 weeks after the last dose of Cotellic.

A Saudi patient should arrive at the medical oncology conversation with the most recent diagnostic workup: pathology report with histology and BRAF biomarker results, contrast CT or PET-CT, brain MRI, baseline ophthalmologic report with OCT, baseline echocardiogram with LVEF, baseline LFTs and CK, and the full treatment history.

The Saudi prescribing and supply picture, plainly

In 2026 the kingdom centres with active BRAF/MEK combination prescribing include KFSHRC Riyadh and Jeddah, KAMC Riyadh under NGHA, KFMC Riyadh, KFH Dammam, and KAUH Jeddah. Cotellic is SFDA-registered for the melanoma indication. The pathway:

1. Diagnosis and BRAF V600 molecular confirmation at the diagnosing centre's pathology lab or a regional reference lab. Turnaround for BRAF V600 IHC is 3 to 7 days; PCR adds a few days; NGS panels typically take 2 to 4 weeks. 2. Multidisciplinary melanoma tumour board review documenting the BRAF V600-positive rationale, the choice of Cotellic plus Zelboraf doublet versus an alternative BRAF/MEK doublet versus the IMspire150 triplet, and the treatment plan. 3. Insurance pre-authorisation for BOTH Cotellic AND Zelboraf in a single combined-rationale submission. CCHI-regulated private insurers and the institutional pathways for Saudi nationals (MOH, NGHA, MOD, MOI) all expect the two-drug rationale and not a single-drug submission. Pre-authorisation typically takes 7 to 14 days for a complete file. 4. Named-patient supply if the SFDA combination-label scope or local stock requires it. Reserve Meds supports the documentation pack and Roche regional liaison. 5. Synchronised pharmacy dispense of Cotellic and Zelboraf on a 28-day refill cycle. If the triplet with Tecentriq is in use, the infusion schedule runs in parallel at the prescribing centre's infusion suite. 6. Ongoing monitoring labs, ophthalmologic surveillance, and echocardiogram per the schedule below.

Cost band

The cost framing for Cotellic is always a combination cost. For the Cotellic plus Zelboraf doublet, the US list price for Cotellic at the standard dose is approximately USD 10,000 to USD 11,000 per 28-day cycle; Zelboraf adds approximately USD 10,000 to USD 12,000 per month. The combined regimen US list price is approximately USD 20,000 to USD 23,000 per month, with an annual combined cost of approximately USD 220,000 to USD 280,000. At indicative 2026 cross rates, the annual combined cost translates to approximately SAR 825,000 to SAR 1.05 million. The IMspire150 triplet adds the Tecentriq cost (approximately USD 14,000 to USD 16,000 per 21-day cycle) for an additional annual cost band that depends on duration of triplet use.

Total cost of care additions include the medical oncologist's monthly consultation, monitoring laboratory fees every 2 weeks for the first 6 months then monthly, ophthalmology visits at month 1, month 3, and every 3 months thereafter, echocardiogram at week 4 and quarterly, dermatology surveillance every 8 weeks, and imaging every 8 to 12 weeks. These add 8 to 18 percent to the combined drug cost base in Saudi private-sector settings. MOH, NGHA, MOD, and MOI institutional pathways for Saudi nationals cover BRAF-targeted melanoma combinations on the institutional formulary at the prescribing institution.

What to expect on Cotellic, week-by-week

The toxicity signature of Cotellic plus Zelboraf is dominated by three distinctive adverse events that are not optional discussion items in the first counselling visit:

- **Photosensitivity**: severe and onset early. Most patients report photosensitivity reactions within the first 1 to 2 weeks. The Saudi UV-intense climate amplifies the operational burden. Mandatory SPF 50+ broad-spectrum sunscreen reapplied every 2 hours when outdoors, long-sleeved protective clothing, broad-brimmed hat, UV-blocking sunglasses, and avoidance of midday outdoor exposure. - **Retinopathy**: serous retinopathy (subretinal fluid accumulation) and rarely retinal vein occlusion. Serous retinal changes can appear as early as the first cycle. Any new visual symptom (blurred vision, scotoma, photopsia, distorted central vision) prompts urgent ophthalmology review with OCT. Routine ophthalmology surveillance at month 1, month 3, and every 3 months. - **Cardiomyopathy**: asymptomatic LVEF decline is detected at the week-4 echocardiogram in a meaningful minority of patients. Routine echocardiogram at baseline, week 4, then quarterly. Dose interruption per protocol for clinically significant LVEF decline.

Other recognised toxicities include diarrhoea (very common, generally manageable with loperamide), nausea and vomiting (anti-emetic premedication and supportive care), fever (pyrexia within the first cycle), peripheral oedema, rash, hepatotoxicity with AST/ALT elevation requiring monthly LFT monitoring, rhabdomyolysis with CK elevation requiring monthly CK monitoring, and hemorrhage. The patient stays on the combination for as long as there is clinical benefit and tolerability, typically 12 months or longer for responders.

When Cotellic is the wrong drug

Cotellic plus Zelboraf is not the right answer for:

- BRAF wild-type melanoma. The biomarker gate is non-negotiable. BRAF wild-type disease routes to immune checkpoint inhibitor therapy (nivolumab plus ipilimumab; pembrolizumab; nivolumab plus relatlimab) or other targeted therapies depending on biomarker profile. - Prior clinically significant retinopathy (history of central serous retinopathy, retinal vein occlusion, or other retinal disease that an ophthalmologist judges incompatible with the Cotellic class signal). - Baseline LVEF below institutional threshold or history of clinically significant cardiomyopathy. - Severe photosensitivity intolerance or photosensitive dermatological conditions (porphyria, severe polymorphic light eruption) that make sustained sun avoidance impractical. - Concurrent strong CYP3A4 inhibitors or inducers where dose adjustment cannot be achieved cleanly. - Severe hepatic impairment (Child-Pugh C). - Pregnancy. - A patient for whom the treating medical oncologist prefers an alternative BRAF/MEK combination (Tafinlar plus Mekinist, or Braftovi plus Mektovi) on tolerability or physician-familiarity grounds. Reserve Meds does not promote one BRAF/MEK combination over another.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We build the document pack (pathology report, BRAF molecular diagnostic results, contrast CT or PET-CT, brain MRI, baseline ophthalmologic report with OCT, baseline echocardiogram with LVEF, baseline LFTs and CK, treatment history, oncologist clinical rationale letter for the combination), submit first-review requests to the chosen Saudi prescribing centre, coordinate the insurance pre-authorisation conversation for Cotellic AND Zelboraf in parallel, support the named-patient regulatory liaison if local supply requires it, set up the first synchronised dispense of both drugs, and stay with the case through the refill cycle. Clinical decisions remain with your treating medical oncologist and the multidisciplinary melanoma tumour board.

Start your case at reservemeds.com. We respond within one business day in English or Arabic.

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.

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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