

## Elahere

Bahrain · access guide

# How to access Elahere for FR $\alpha$ -positive platinum-resistant ovarian cancer from Bahrain: 2026 pathway via Bahrain Oncology Center with cross-border FOLR1 IHC and named-patient supply

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

Elahere (mirvetuximab soravtansine-gynx) is the first antibody-drug conjugate approved for platinum-resistant ovarian cancer and the first folate receptor alpha (FR $\alpha$ )-directed therapy approved for any indication. AbbVie acquired ImmunoGen for USD 10.1 billion in February 2024 primarily to bring this drug into its oncology portfolio. The FDA converted the November 2022 accelerated approval to full traditional approval in March 2024 based on the MIRASOL Phase 3 randomised trial, which demonstrated a statistically significant overall survival benefit (median 16.46 months vs 12.75 months on investigator-choice chemotherapy). For a Bahrain-resident adult woman with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer whose tumor pathology shows FR $\alpha$ -positive expression at the labelled threshold, Elahere is the first targeted therapy with overall survival benefit in a setting historically defined by 12 to 14 month median survival.

This page explains the pathway in 2026 for a Bahrain-resident adult: the FR $\alpha$  biomarker gate that requires cross-border pathology referral (in-country FOLR1 IHC capability is limited), eligibility, the Bahrain Oncology Center reference and BDF Hospital and Salmaniya Medical Complex adult oncology infrastructure, the every-3-week IV schedule with boxed-warning ocular toxicity protocol, NHRA-equivalent named-patient supply, cost in BHD, and the psychosocial dimensions.

## Why Elahere, and why the FR $\alpha$ biomarker comes first

Elahere is a humanised IgG1 kappa monoclonal antibody (mirvetuximab) targeting folate receptor alpha, conjugated via a cleavable disulfide linker to the maytansinoid microtubule inhibitor payload DM4, with a drug-antibody ratio of approximately 3.4. The mechanism is FR $\alpha$ -mediated tumor cell internalisation, intracellular DM4 release, microtubule disruption, mitotic arrest, and apoptosis.

Folate receptor alpha is highly expressed on approximately 35 to 40 percent of epithelial ovarian cancers at the high-expression threshold (PS2+ staining in at least 75 percent of viable tumor cells by FDA-approved companion diagnostic) that defines Elahere eligibility. Without a confirmed FR $\alpha$ -positive tumor by the Roche VENTANA FOLR1 (FOLR1-2.1) RxDx Assay or an equivalent validated IHC method, Elahere is not indicated.

For a Bahrain patient the operational order is: (1) the treating gynaecologist or medical oncologist at Bahrain Oncology Center, BDF Hospital, or Salmaniya Medical Complex confirms platinum-resistant disease (progression within 6 months of last platinum, per GCIG) and 1 to 3 prior systemic lines; (2) the tumor block is shipped cross-border to a regional reference pathology service for FOLR1 IHC (KFSHRC Riyadh is the closest established reference with 5 to 7 day in-house turnaround, plus shipping); (3) ONLY IF FR $\alpha$ -positive at the PS2+ greater-than-or-equal-to 75 percent threshold does the Elahere eligibility conversation move forward; (4) if FR $\alpha$ -negative or FR $\alpha$ -low, the pathway pivots to standard platinum-resistant chemotherapy, bevacizumab combinations, PARP inhibitor maintenance for eligible patients, or clinical trial enrolment.

## **What Elahere is, in plain language**

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Elahere is an intravenous infusion every 3 weeks at 6 mg/kg adjusted ideal body weight. First infusion runs over 1 hour through a 0.2 micron in-line filter; subsequent infusions over 30 minutes if tolerated. Premedications before each infusion: corticosteroid (dexamethasone 10 mg IV), antihistamine (diphenhydramine 25 to 50 mg IV), antipyretic (paracetamol 650 to 1000 mg orally), anti-emetic per protocol. Ophthalmic supportive regimen around every infusion: prednisolone acetate 1 percent drops 6 times daily for the day before, day of, and 4 days after infusion; lubricating preservative-free artificial tears at least 4 times daily continuously through the course; cycloplegic drops if pre-existing dry eye. Treatment continues until disease progression or unacceptable toxicity.

## **Eligibility at a Bahraini gynaecologist or medical oncologist clinic**

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1. Confirmed platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer (progression within 6 months of last platinum, per GCIG). 2. One to three prior systemic regimens. 3. FR $\alpha$ -positive tumor: at least 75 percent PS2+ on FOLR1 IHC. Load-bearing gate. 4. ECOG 0 or 1 (ECOG 2 case by case). 5. Adequate marrow, liver, renal function per labelled cutoffs. 6. No active ocular disease; pre-existing dry eye or mild prior keratopathy requires baseline ophthalmology and tailored supportive regimen. 7. No grade 3 or higher peripheral neuropathy at baseline. 8. Pregnancy excluded; effective contraception during treatment and for 7 months after last dose.

A Bahrain patient should arrive with original pathology report, current imaging, CA-125 trend, complete prior treatment history with response durations, current labs, baseline ophthalmology, and a representative tumor block released for cross-border FOLR1 IHC referral.

## **The Bahrain administration picture, plainly**

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The Bahrain adult gynaecology and medical oncology network covering Elahere in 2026 includes:

- Bahrain Oncology Center (King Hamad University Hospital), the adult medical oncology and gynaecology reference for the kingdom.
- BDF Hospital, with adult medical oncology.
- Salmaniya Medical Complex, with adult medical oncology.
- King Hamad University Hospital ophthalmology service, the in-country partner for the every-2-cycle ocular monitoring rhythm.

In-country FOLR1 IHC pathology capability is not yet established in Bahrain as of 2026; tumor blocks ship cross-border to KFSHRC Riyadh or a European reference laboratory with 10 to 14 day total turnaround including shipping.

Bahrain NHRA is the regulator and has a mature ATMP framework (2019) supportive of named-patient supply. AbbVie regional commercial coordination via the Middle East office. Elahere is within the 24-month post-FDA-full-approval window; Bahrain NHRA registration status VERIFY at intake. Where domestic registration is in progress, the named-patient pathway via the NHRA single-patient import authorisation is the operational supply route.

For Bahraini patients where the in-country oncology capability is not aligned with the case complexity or where the family prefers an established regional ADC programme, cross-border referral to KFSHRC Riyadh (1 hour by road via King Fahd Causeway) is a standard operational option; the MoH treatment-abroad funding pathway applies for Bahraini nationals where the clinical case meets the funding criteria.

## **The 2026 pathway, step by step**

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Week 0 to 2: Reserve Meds assembles the document pack with the treating oncologist at Bahrain Oncology Center or BDF or Salmaniya and arranges release of the most recent representative tumor block for cross-border FOLR1 IHC referral.

Week 2 to 4: FOLR1 IHC at the regional reference pathology service (KFSHRC Riyadh or equivalent) with 10 to 14 day total turnaround including shipping. THIS IS THE GATE. If FR $\alpha$ -positive at the labelled threshold the pathway proceeds. If FR $\alpha$ -negative or FR $\alpha$ -low the conversation pivots to non-Elahere options.

Week 4: Baseline ophthalmology examination at King Hamad University Hospital or partner ophthalmology service. Financial pre-authorisation conversation in parallel. Bahraini nationals: MoH treatment-abroad funding where cross-border referral is in play; in-country MoH funding for high-cost oncology biologics where treatment is administered locally; pre-authorisation against the FDA labelled indication and FR $\alpha$ -positive pathology is the gating step. Bahrain-resident expatriates: employer-sponsored cover or self-pay; pre-authorisation against the labelled indication with oncology benefit ceilings reviewed. AbbVie patient-access programmes for the GCC explored where coverage is partial.

Week 5: First infusion at Bahrain Oncology Center, BDF Hospital, or cross-border at KFSHRC Riyadh depending on operational choice. Day 0 of the Elahere clock. Premedications, 1-hour first infusion, observation period for infusion reactions. Ophthalmic drop protocol begins.

Cycles 2 onwards: every-3-week infusion (30 minutes from cycle 2 if first dose tolerated). Ophthalmology every 2 cycles for the first 8 cycles. CA-125 every cycle. Imaging response assessment every 6 to 9 weeks. Treatment continues until progression, intolerable toxicity, or patient decision.

## **Boxed warning ocular toxicity protocol**

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Elahere carries an FDA boxed warning for ocular toxicity. Approximately 50 percent of patients develop some grade of visual symptom (blurred vision, dry eye, photophobia, keratopathy, cataract, keratitis); approximately 9 percent develop grade 3 to 4 ocular AEs. Onset typically within the first 2 to 4 cycles. The operational discipline is non-negotiable: baseline ophthalmology before first dose; ophthalmology every 2 cycles for the first 8 cycles; any patient-reported visual change triggers urgent ophthalmology review; ophthalmic drop schedule is part of treatment; dose modification per CTCAE grade. The MDT includes an ophthalmologist familiar with ADC-class ocular AEs or willing to develop the protocol; for Bahrain-treated patients this typically means the King Hamad University Hospital ophthalmology service in partnership with the treating oncologist.

## Cost expectation in BHD

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US wholesale acquisition cost approximately USD 28,000 per 100 mg vial. A 70 kg patient at 6 mg/kg AIBW uses approximately 4 vials per cycle, approximately USD 112,000 per cycle. With median 8 to 10 cycles in MIRASOL, treatment course cost is approximately USD 950,000 to USD 1.2 million. BHD-equivalent at 2026 indicative cross rates is approximately BHD 360,000 to BHD 450,000 per treatment course.

For Bahraini nationals: MoH funding for high-cost oncology biologics is the standard pathway; MoH treatment-abroad funding where cross-border referral is in play. For Bahrain-resident expatriates: employer-sponsored commercial cover or self-pay; oncology annual benefit ceilings reviewed case by case. AbbVie patient-access programmes for the GCC are an active operational pathway where coverage is partial.

## Monitoring and mental-health screening

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Per-cycle laboratory monitoring: CBC with differential, comprehensive metabolic panel including AST, ALT, total bilirubin, creatinine, CA-125. Per-cycle symptom monitoring: vision, peripheral neuropathy, fatigue, nausea, diarrhea, abdominal pain. Pneumonitis risk low but present.

Platinum-resistant ovarian cancer carries a median overall survival under 18 months on standard chemotherapy. Elahere extends survival to a median 16.5 months in MIRASOL but is not curative. The MDT integrates baseline and periodic mental-health screening from day one: PHQ-9 depression screen at baseline and every 2 to 3 cycles; caregiver-burden screening at baseline and 3-month intervals; routine social work involvement; low threshold for psychiatric referral.

## Religious, ethical, and family-logistics framing

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Elahere is a recombinant monoclonal antibody manufactured in mammalian cell culture (CHO cells) conjugated to a small-molecule cytotoxic payload. No porcine, bovine, or human-derived component is used in the final product. The infusion is permissible across MENA Islamic jurisprudence on the same footing as other recombinant biologic and ADC therapies.

The decision to proceed with treatment, to limit treatment scope, or to transition to comfort care is a family decision in consultation with the treating gynaecologist. The every-3-week infusion schedule, the every-2-cycle ophthalmology rhythm, and the daily ophthalmic drop regimen create a sustained operational load on the patient and the primary caregiver; family involvement in the ophthalmic drop schedule is part of the protocol for many patients. For Bahraini patients treated cross-border at KFSHRC Riyadh, the every-3-week travel rhythm requires deliberate family logistics planning.

## When Elahere is NOT the right option

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- FR $\alpha$ -negative or FR $\alpha$ -low tumor: Elahere not indicated; pathway pivots to standard platinum-resistant chemotherapy, bevacizumab combinations, PARP inhibitor maintenance for eligible patients, or clinical trial enrolment. - More than 3 prior lines: outside the labelled indication. - Active grade 3 or higher peripheral neuropathy: defer. - Active corneal disease or recent ocular surgery: defer. - Pregnancy or refusal of effective contraception: contraindicated. - ECOG 3 or 4: not labelled. - Platinum-sensitive disease: not yet the labelled indication; clinician-discretion named-patient use only.

Reserve Meds does not push a default. If FOLR1 IHC returns FR $\alpha$ -negative or FR $\alpha$ -low, or if the conversation with the treating physician points elsewhere, the operational pathway shifts accordingly and we coordinate that pathway instead.

## What Reserve Meds does on this case

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We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Bahrain Elahere case we build the document pack, arrange the cross-border FOLR1 IHC pathology referral (typically to KFSHRC Riyadh) including specimen shipping, coordinate baseline ophthalmology at King Hamad University Hospital and the every-2-cycle monitoring rhythm, run the MoH funding or commercial pre-authorisation conversation including the MoH treatment-abroad pathway where cross-border treatment is in play, engage AbbVie patient-access programmes where insurance coverage is partial, support the NHRA named-patient supply application where domestic registration is still in progress, and stay with the case through response assessment and progression. Clinical decisions remain with your treating gynaecologist and the multidisciplinary tumour board.

### *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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### Reserve Meds

*reserved for you.*

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

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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