Augtyro

Bahrain · access guide

How to access Augtyro for ROS1-positive non-small-cell lung cancer and NTRK-positive solid tumours from Bahrain: 2026 pathway via Bahrain oncology and regional referral

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

Bahrain's adult medical oncology services run out of King Hamad University Hospital (KHUH), Salmaniya Medical Complex, and Bahrain Specialist Hospital, with established referral pathways to KFSHRC Riyadh, NCCCR Doha, and the UAE oncology centres for cases requiring deeper subspecialty infrastructure. Paediatric NTRK cases age 12 and older typically refer cross-border to KFSHRC paediatric oncology or to Sidra Medicine via the MoH treatment-abroad pathway. Augtyro (repotrectinib) is a Bristol Myers Squibb next-generation tyrosine kinase inhibitor covering ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) in adults and NTRK gene fusion-positive solid tumours in adults and paediatric patients age 12 years and older. The FDA approved ROS1 in November 2023 and expanded to NTRK fusions in June 2024. The Bahrain supply route in 2026 most commonly runs through the named-patient programme (NPP) pathway via the National Health Regulatory Authority (NHRA).

This page explains how the pathway works in 2026 for a Bahrain-resident patient: who qualifies, where the diagnostic and molecular workup happens, where the prescription is written and filled, what the realistic out-of-pocket exposure band is in BHD, what to monitor on therapy, and how the multi-year treatment course settles into a Bahraini family's life.

Why Augtyro, and why now

Augtyro is repotrectinib (TPX-0005), discovered at Turning Point Therapeutics, acquired by Bristol Myers Squibb in August 2022. FDA approved November 2023 for ROS1-positive locally advanced or metastatic NSCLC in adults (TRIDENT-1, ORR 79 percent TKI-naive, intracranial ORR 89 percent). Expanded June 2024 to NTRK gene fusion-positive solid tumours in adults and paediatric patients age 12 and older (TRIDENT-1 NTRK cohort, ORR 58 percent TKI-naive).

For a Bahraini patient with confirmed ROS1-positive NSCLC or NTRK-positive solid tumour, Augtyro is the named-patient route for first-line or post-first-generation-TKI treatment under most institutional protocols followed by KHUH, Salmaniya, and Bahrain Specialist Hospital. The eligibility gatekeeper is biomarker confirmation.

What Augtyro is, in plain language

Augtyro is an oral capsule. 160 mg once daily for 14 days (lead-in), then 160 mg twice daily (maintenance), with food. Room temperature storage. No infusion, no inpatient stay, no certified-centre requirement.

The 14-day lead-in is about managing initial dizziness. Driver support during the first two weeks is part of the practical handoff.

For metastatic disease, treatment continues until progression or intolerable toxicity.

Mechanism: macrocyclic next-generation TKI active against ROS1 and NTRK1/2/3 fusions plus the solvent-front resistance mutations that limit first-generation inhibitors. CNS-penetrant.

The biomarker requirement

The eligibility gate is documented ROS1 rearrangement by IHC, FISH, or NGS, or documented NTRK1, NTRK2, or NTRK3 gene fusion by NGS or RNA-based fusion assay. Bahrain pathology services (KHUH, Salmaniya, Bahrain Specialist Hospital) run ROS1 IHC. Confirmatory FISH or NGS, and NTRK fusion testing, typically routes to KFSHRC molecular pathology in Riyadh, NCCCR molecular pathology in Doha, or international reference labs (Caris Life Sciences, Foundation Medicine). NGS turnaround 2 to 6 weeks depending on the route.

If the original biopsy did not include ROS1 or NTRK testing, archived tissue submission or re-biopsy is standard.

The NHRA named-patient supply pathway

Augtyro is a recent FDA-approved oncology drug. NHRA commercial registration status as of mid-2026 is most likely pending or not yet completed. [VERIFY: current NHRA registration status]. The supply route in 2026 most commonly runs through the NHRA named-patient pathway:

1. The prescribing oncologist at KHUH, Salmaniya, or Bahrain Specialist Hospital documents the biomarker-confirmed indication and clinical rationale. 2. The centre's pharmacy and regulatory liaison files the named-patient request with NHRA. 3. The Bristol Myers Squibb regional office coordinates supply, typically through Cigalah or another regional distributor. 4. NHRA approval triggers the first dispense. Typical timeline 4 to 10 weeks for a complete file.

For paediatric NTRK age 12+ cases, the Bahrain MoH treatment-abroad pathway typically refers to KFSHRC paediatric oncology or to Sidra Medicine paediatric oncology, with the Augtyro NPP application handled through the receiving centre's regulatory office.

Eligibility at a Bahrain oncologist's clinic

For Bahrain-resident patients, the medical oncology service applies the FDA approval criteria plus the major-guideline framework:

1. Histologically confirmed solid tumour. 2. Confirmed biomarker: ROS1 rearrangement or NTRK1/2/3 gene fusion. 3. For ROS1-positive metastatic NSCLC: stage IV disease confirmed by contrast CT, PET-CT, and brain MRI. 4. For NTRK-positive solid tumours: locally advanced or metastatic disease. 5. For paediatric NTRK indication: age 12 and older. 6. Baseline labs: CBC, CMP including LFTs, bilirubin, fasting glucose and HbA1c, lipid panel, uric acid. 7. Baseline ECG with QTc. 8. Baseline neurological examination. 9. Baseline pulmonary assessment. 10. Pregnancy and lactation screen; contraception plan documented for women of reproductive potential. 11. Drug interaction screen.

A Bahraini patient should arrive at the oncology referral with the most recent pathology, imaging, and prior treatment history. Reserve Meds organises the documentation pack and supports the NHRA NPP application.

The Bahrain prescribing and dispense picture, plainly

In 2026 the Bahrain oncology centres for Augtyro NPP cases:

- **King Hamad University Hospital (KHUH)**: oncology service with medical oncology and pathology capability. - **Salmaniya Medical Complex**: MoH flagship; medical oncology and the national cancer registry interface. - **Bahrain Specialist Hospital**: private-sector oncology.

For paediatric NTRK age 12+ cases, Bahrain typically does not provide in-country paediatric solid-tumour oncology at the depth required; cross-border referral to KFSHRC paediatric oncology or Sidra Medicine paediatric oncology is the standard route, coordinated via the MoH treatment-abroad office.

The pathway:

1. **Diagnosis and molecular confirmation**: at the diagnosing centre's pathology lab; complex molecular work routed to KFSHRC Riyadh, NCCCR Doha, or international reference labs. 2. **MDT review**: KHUH and Salmaniya run thoracic and molecular tumour boards. Documentation of rationale and treatment plan. 3. **MoH treatment-abroad option**: for cases where the treating physician prefers regional centre management or where subspecialty molecular interpretation is wanted, the MoH treatment-abroad office maintains referral relationships with KFSHRC Riyadh and Cleveland Clinic Abu Dhabi. Cross-border referral is mature. 4. **NHRA NPP application**: prescribing centre's regulatory liaison files. BMS regional office coordinates supply. 5. **Insurance and government coverage**: for Bahraini nationals, MoH institutional coverage at KHUH or Salmaniya subject to NHRA NPP approval. For private-insured residents (AXA Gulf, Bahrain National Insurance, GIG Bahrain, regional Bupa products), prior authorisation runs case-by-case given NPP status. 6. **Pharmacy dispense**: prescribing centre's pharmacy fills the first 30-day supply with full counselling on the 14-day lead-in. 7. **Refill cycle**: monthly with continued monitoring documentation.

Cost expectation in BHD

US list price (2026) for Augtyro at the maintenance dose is approximately USD 25,000 to USD 30,000 per 30-day supply, annual approximately USD 300,000 to USD 360,000. At indicative 2026 cross rates, a 30-day supply at USD 27,500 is approximately BHD 10,400, and annual cost at USD 330,000 is approximately BHD 124,000.

For Bahraini-national families on MoH coverage, Augtyro is dispensed through the institutional formulary at KHUH or Salmaniya subject to NHRA NPP approval. For expatriate residents and self-pay families, the pharmacy issues a separated quote. Bristol Myers Squibb regional access programmes may underwrite portions of the cost during NPP.

Monitoring on therapy

- **Neurological examination**: monthly for the first 3 months, then quarterly or symptom-driven. - **LFTs**: every 2 to 4 weeks for the first 3 months, then monthly to quarterly. - **CBC**: every 2 to 4 weeks for the first 3 months, then monthly. - **Fasting glucose and HbA1c**: monthly for the first 3 months, then quarterly. - **Lipid panel**: baseline and every 3 to 6 months. - **Uric acid**: baseline and as clinically indicated. - **ECG**: as clinically indicated. - **Pulmonary symptoms**: trigger HRCT and pulmonology input for pneumonitis or ILD. - **Disease assessment**: contrast CT or PET-CT every 8 to 12 weeks; brain MRI every 12 weeks if CNS metastases at baseline.

Religious, ethical, and family-logistics framing

Augtyro is an oral small molecule with no animal-source material. Halal and kosher acceptability are not in question. The family-logistics burden sits in the 14-day lead-in, the chronic twice-daily dosing, and the multi-pillar monitoring routine. For paediatric NTRK cases referred cross-border, the family travels for the initial workup and dispense, then returns to Bahrain for subsequent refill cycles under the local oncology service's supervision.

When Augtyro is not the right call

Augtyro is not appropriate for ROS1-negative and NTRK-negative disease, patients with significant interstitial lung disease history, severe pre-existing cognitive impairment, uncontrolled hyperglycaemia, or pregnancy. For confirmed ROS1-positive disease where Augtyro is not chosen, alternatives are entrectinib and crizotinib. For confirmed NTRK-positive disease where Augtyro is not chosen, alternatives are larotrectinib and entrectinib. Reserve Meds does not promote one ROS1 or NTRK 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 Bahrain Augtyro case we build the document pack, coordinate the Bahrain-side oncology referral and the MoH treatment-abroad pathway if relevant, support the NHRA NPP application or the receiving centre's NPP application for cross-border cases, support the insurance and government coverage conversation, set up the first dispense at the chosen pharmacy, and stay with the case through the refill cycle. Clinical decisions remain with your treating medical oncologist or paediatric oncologist 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.

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.
reservemeds.com · hello@reservemeds.com