

## Augtyro

Kuwait · access guide

# How to access Augtyro for ROS1-positive non-small-cell lung cancer and NTRK-positive solid tumours from Kuwait: 2026 pathway via Kuwait Cancer Control Center and regional referral

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

Kuwait's adult oncology pathway runs principally through the Kuwait Cancer Control Center (KCCC), with Amiri Hospital oncology and other Ministry of Health institutional sites providing supporting capacity. Paediatric NTRK age 12 and older cases typically refer cross-border to KFSHRC paediatric oncology or Sidra Medicine paediatric oncology via the MoH Foreign Medical Treatment Office. 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 Kuwait supply route in 2026 most commonly runs through the named-patient programme (NPP) pathway via the MoH Drug and Food Control Administration (DFC).

This page explains how the pathway works in 2026 for a Kuwait-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 KWD, what to monitor on therapy, and how the multi-year treatment course settles into a Kuwaiti 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.

## 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**

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Confirmed ROS1 rearrangement by IHC, FISH, or NGS, or confirmed NTRK1, NTRK2, or NTRK3 gene fusion by NGS or RNA-based fusion assay.

KCCC molecular pathology runs ROS1 IHC and basic FISH. NGS panels and complex NTRK fusion testing typically route to KFSHRC molecular pathology, NCCCR molecular pathology, or international reference labs (Caris Life Sciences, Foundation Medicine). NGS turnaround 2 to 6 weeks.

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

## **The MoH DFC named-patient supply pathway**

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

1. The prescribing oncologist at KCCC or Amiri Hospital documents the biomarker-confirmed indication and clinical rationale. 2. The centre's pharmacy and regulatory liaison files the named-patient request with MoH DFC. 3. The Bristol Myers Squibb regional office coordinates supply. 4. MoH DFC approval triggers the first dispense. Typical timeline 4 to 10 weeks for a complete file.

For paediatric NTRK age 12+ cases, the Kuwait MoH Foreign Medical Treatment Office handles cross-border referral and coordinates the Augtyro NPP application through the receiving centre's regulatory office (KFSHRC paediatric oncology or Sidra Medicine paediatric oncology).

## **Eligibility**

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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 Kuwaiti 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 MoH DFC NPP application.

## **The Kuwait prescribing and dispense picture, plainly**

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In 2026 the Kuwait oncology centres for Augtyro NPP cases:

- **Kuwait Cancer Control Center (KCCC)**: the national adult cancer reference centre. Active thoracic and molecular tumour board. Routes adult ROS1-positive NSCLC and adult NTRK-positive solid tumour cases. - **Amiri Hospital oncology**: MoH oncology service.

For paediatric NTRK age 12+ cases, cross-border referral to KFSHRC paediatric oncology or Sidra Medicine paediatric oncology is the standard route, coordinated via the MoH Foreign Medical Treatment Office.

The pathway:

1. **Diagnosis and molecular confirmation**: at KCCC pathology or the diagnosing centre; complex molecular work routed to KFSHRC, NCCCR, or international reference labs. 2. **MDT review**: KCCC runs the adult thoracic and molecular tumour boards. 3. **MoH Foreign Medical Treatment Office option**: for cases where the treating physician prefers regional centre management, the FMTO maintains referral relationships with KFSHRC Riyadh and other regional reference centres. 4. **MoH DFC NPP application**: prescribing centre's regulatory liaison files. BMS regional office coordinates supply. 5. **Insurance and government coverage**: for Kuwaiti nationals, MoH institutional coverage at KCCC or Amiri subject to DFC NPP approval. National Health Insurance Authority (NHIA) Afya coverage may apply for some expatriate residents. For private insurance, prior authorisation runs case-by-case given NPP status. 6. **Pharmacy dispense**: KCCC 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 KWD

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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 KWD 8,400, and annual cost at USD 330,000 is approximately KWD 101,000.

For Kuwaiti-national families on MoH coverage, Augtyro is dispensed through the institutional formulary at KCCC subject to DFC 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

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- **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. - **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

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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 initial workup and the first dispense, then returns to Kuwait for subsequent refill cycles under the local oncology service's supervision.

## When Augtyro is not the right call

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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

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We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Kuwait Augtyro case we build the document pack, coordinate the KCCC or cross-border oncology referral as appropriate, support the MoH DFC 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, 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.

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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.

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