Augtyro

Saudi Arabia · access guide

How to access Augtyro for ROS1-positive non-small-cell lung cancer and NTRK-positive solid tumours from Saudi Arabia: 2026 pathway via KFSHRC, KAMC, KFMC, and the wider kingdom oncology network

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

Saudi Arabia operates one of the deepest national oncology networks in the wider region. King Faisal Specialist Hospital and Research Centre in Riyadh and Jeddah (KFSHRC), King Abdulaziz Medical City Riyadh (KAMC) and the National Guard Health Affairs sites, King Fahad Medical City Riyadh (KFMC), Princess Noorah Oncology Centre Jeddah, and the Dr Sulaiman Al Habib oncology network all run medical, thoracic, and where relevant paediatric oncology services that diagnose, biomarker-test, and treat solid tumours driven by rare molecular drivers. Augtyro (repotrectinib) is a Bristol Myers Squibb next-generation tyrosine kinase inhibitor covering two distinct biomarker-defined populations: ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) in adults, and NTRK gene fusion-positive solid tumours in adults and in paediatric patients age 12 years and older. The FDA approved the ROS1 indication in November 2023 and expanded to NTRK fusions in June 2024. The Saudi supply route in 2026 most commonly runs through the named-patient programme (NPP) pathway via the Saudi Food and Drug Authority (SFDA) rather than through a fully registered commercial channel. For a Saudi patient with newly diagnosed ROS1-positive metastatic NSCLC, or for any Saudi patient with an NTRK fusion-positive solid tumour for whom Augtyro is the chosen treatment, the operational question is which kingdom prescribing centre fits the case, how the molecular diagnostic confirmation and the SFDA NPP application proceed in parallel, and how the long-term refill cycle integrates with multi-year treatment.

This page explains how the pathway works in 2026 for a Saudi-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 SAR, what to monitor on therapy, and how the treatment plan fits into a Saudi family's life. It is concierge documentation written for a family already in conversation with a treating oncologist.

Why Augtyro, and why now

Augtyro is repotrectinib (development code TPX-0005), discovered at Turning Point Therapeutics in San Diego, acquired by Bristol Myers Squibb in August 2022 for USD 4.1 billion. FDA approval came in November 2023 for ROS1-positive locally advanced or metastatic NSCLC in adults, both TKI-naive and post-crizotinib settings. The June 2024 expansion added NTRK gene fusion-positive solid tumours in adults and paediatric patients age 12 and older. Both approvals were based on the TRIDENT-1 trial.

For a Saudi patient with newly diagnosed ROS1-positive metastatic NSCLC, the TRIDENT-1 TKI-naive cohort is the central decision input: objective response rate 79 percent, median duration of response 34.1 months, intracranial objective response rate 89 percent in patients with measurable baseline CNS metastases. For a Saudi patient with ROS1-positive disease post-crizotinib, the post-crizotinib cohort showed an objective response rate of 38 percent with activity retained against the G2032R solvent-front resistance mutation that limits crizotinib and entrectinib. For NTRK-positive solid tumours, TRIDENT-1 showed an objective response rate of 58 percent in TKI-naive patients and 50 percent in TKI-pretreated patients across NTRK1, NTRK2, and NTRK3 fusions and across multiple tumour histologies (thyroid, sarcoma, salivary gland, NSCLC, colorectal).

What Augtyro is, in plain language

Augtyro is an oral capsule. The dosing schedule is distinctive:

- **Days 1 to 14 (lead-in)**: 160 mg orally once daily, with food. - **Day 15 onward (maintenance)**: 160 mg orally twice daily, twelve hours apart, with food.

The 14-day lead-in is about managing initial dizziness, which is the dose-limiting toxicity for many patients in the first 1 to 2 weeks. Tolerance develops with continued dosing. Patients should expect some dizziness in the first week or two that improves over time, should not drive or operate machinery during the lead-in if they feel impaired, and should have family or driver support arranged for the first two weeks.

Storage is room temperature. There is no infusion, no inpatient stay, no certified-centre requirement. For metastatic disease, treatment continues until progression or intolerable toxicity.

The mechanism: ROS1 or NTRK fusion produces a constitutively active fusion kinase. Augtyro is a macrocyclic next-generation TKI; the closed-ring scaffold confers activity against the solvent-front resistance mutations (ROS1 G2032R, TRKA G595R, TRKB G639R, TRKC G623R) that emerge on first-generation inhibitors. Augtyro is CNS-penetrant.

The biomarker requirement

The eligibility gate is documented ROS1 rearrangement (IHC, FISH, or NGS) or documented NTRK1, NTRK2, or NTRK3 gene fusion (NGS or RNA-based fusion assay).

Saudi-side molecular diagnostic capability is deepest at KFSHRC's molecular pathology service, which runs comprehensive solid-tumour NGS in-house and is one of the regional reference labs. KAMC and KFMC pathology run parallel capability. Regional and international reference labs (Caris Life Sciences, Foundation Medicine) handle complex NGS or RNA-fusion work where local capability is constrained. NGS turnaround in Saudi settings is typically 2 to 4 weeks. If the original biopsy did not include ROS1 or NTRK testing, archived tissue submission to a reference lab or re-biopsy is standard.

The SFDA named-patient supply pathway

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

1. The prescribing oncologist at KFSHRC, KAMC, KFMC, Princess Noorah, or Dr Sulaiman Al Habib documents the biomarker-confirmed indication and clinical rationale. 2. The prescribing centre's regulatory office files the named-patient request with SFDA, including molecular pathology, imaging, staging, prior treatment history, and MDT recommendation. 3. The Bristol Myers Squibb regional office coordinates supply, typically through the centre's institutional distributor agreement or through a designated regional partner. 4. SFDA NPP approval triggers the first dispense. Typical end-to-end timeline from MDT recommendation through SFDA NPP approval to first dispense is 4 to 10 weeks for a complete file.

This is not unusual for recent FDA-approved oncology drugs in the kingdom. The SFDA pathway for biomarker-defined indications is well-established.

Eligibility at a Saudi oncologist's clinic

For Saudi-resident patients, the medical, thoracic, and paediatric oncology services apply the FDA approval criteria plus the major-guideline framework:

1. Histologically confirmed solid tumour. For ROS1, NSCLC (predominantly adenocarcinoma). 2. Confirmed biomarker: ROS1 rearrangement by IHC, FISH, or NGS, or NTRK1, NTRK2, or NTRK3 fusion by NGS or RNA-based fusion assay. 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 per tumour-type staging. 5. For the paediatric NTRK indication: age 12 and older. 6. Baseline labs: complete blood count, comprehensive metabolic panel including LFTs, bilirubin, fasting glucose and HbA1c, lipid panel, uric acid. 7. Baseline ECG with QTc. 8. Baseline neurological examination with cognitive, gait, coordination, and sensory baseline. 9. Baseline pulmonary assessment. 10. Pregnancy and lactation screen; contraception plan documented for women of reproductive potential and for adolescent patients of reproductive potential in the paediatric NTRK setting. 11. Drug interaction screen including herbal products and grapefruit.

A Saudi patient should arrive at the oncology referral with the most recent pathology, contrast CT or PET-CT, brain MRI where relevant, and prior treatment history. Reserve Meds organises the documentation pack and supports the SFDA NPP application in parallel.

The Saudi prescribing and dispense picture, plainly

In 2026 the Saudi oncology centres with active Augtyro NPP experience include:

- **King Faisal Specialist Hospital and Research Centre Riyadh and Jeddah**: the kingdom's deepest comprehensive oncology and molecular diagnostics service. KFSHRC thoracic oncology and molecular tumour board reviews all complex molecular-driver cases including ROS1-positive NSCLC and NTRK-positive solid tumours. KFSHRC paediatric oncology covers the paediatric NTRK indication. - **King Abdulaziz Medical City Riyadh**: the flagship National Guard Health Affairs site with adult medical and paediatric oncology services. - **King Fahad Medical City Riyadh**: MoH flagship comprehensive oncology centre. - **Princess Noorah Oncology Centre Jeddah**: dedicated MoH oncology centre in the western region. - **Dr Sulaiman Al Habib oncology network** (Riyadh, Khobar, Qassim, and other sites): the largest private-sector oncology footprint.

The pathway:

1. **Diagnosis and molecular confirmation**: at the diagnosing centre's pathology lab or sent to KFSHRC molecular pathology, KAMC pathology, KFMC pathology, or an international reference lab. NGS turnaround 2 to 4 weeks. 2. **MDT review**: thoracic / molecular tumour board for adult ROS1-positive NSCLC; the relevant disease-specific MDT for adult NTRK solid tumours; paediatric tumour board for paediatric NTRK cases. 3. **SFDA NPP application**: prescribing centre's regulatory office files. BMS regional office coordinates supply. 4. **Insurance and government coverage**: for Saudi nationals, the institutional MoH or Council of Cooperative Health Insurance (CCHI) pathway covers the drug cost. For private insurance (Bupa Arabia, Tawuniya, MedGulf, AXA Cooperative), Augtyro coverage runs through case-by-case prior authorisation given NPP status. Documentation requirement includes biomarker confirmation, MDT recommendation, SFDA NPP approval, and a clinical rationale letter. 5. **Pharmacy dispense**: prescribing centre's pharmacy or partnered specialty pharmacy fills the first 30-day supply with full counselling on the 14-day lead-in. 6. **Refill cycle**: monthly with continued monitoring documentation.

Cost expectation in SAR

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 SAR 103,000, and annual cost at USD 330,000 is approximately SAR 1.24 million.

Total cost of care additions include oncology consultation fees, monitoring labs, imaging, endocrinology and neurology input where relevant, and supportive care. These add 5 to 15 percent to the drug cost base in private-sector settings.

For Saudi-national families on MoH or CCHI coverage, Augtyro is dispensed through the institutional formulary at KFSHRC, KAMC, KFMC, or Princess Noorah subject to SFDA NPP approval. For private-insured families, the pharmacy issues a separated quote: drug cost, monitoring labs, imaging, oncology visits, and any Reserve Meds coordination fee disclosed in writing. Bristol Myers Squibb regional access programmes may underwrite portions of the cost during the NPP phase.

Monitoring on therapy

- **Neurological examination**: monthly for the first 3 months, then quarterly or symptom-driven. Dizziness dose-limiting in week 1 to 2. Paraesthesia, dysgeusia, and possible cognitive disturbance or mood change require attention. - **Liver function tests**: every 2 to 4 weeks for the first 3 months, then monthly to quarterly. - **Complete blood count**: every 2 to 4 weeks for the first 3 months, then monthly. Anaemia is the most common haematological AE. - **Fasting glucose and HbA1c**: monthly for the first 3 months, then quarterly. Hyperglycaemia requires endocrinology input where new-onset or worsening. - **Lipid panel**: baseline and every 3 to 6 months. - **Uric acid**: baseline and as clinically indicated. - **ECG**: as clinically indicated. - **Pulmonary symptoms**: dyspnoea, cough, or fever triggers 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

Augtyro is an oral small molecule. No animal-source material, no donor cells, no blood product. Halal and kosher acceptability are not in question. The classical Islamic jurisprudential framework for chronic medication in life-threatening illness endorses the treatment shape.

The family-logistics burden of Augtyro sits in three places: the 14-day lead-in with the dizziness signal, the chronic twice-daily dosing schedule taken with food, and the multi-pillar monitoring routine. The first 30 to 60 days are the operational pivot. Adherence support and family co-monitoring are part of the practical handoff. For paediatric NTRK age 12+ patients, the parent or guardian alongside the patient handles adherence and symptom reporting within the paediatric oncology counselling framework.

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, patients with severe pre-existing cognitive impairment, patients with uncontrolled hyperglycaemia until stabilised, 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; the decision sits with the treating oncologist and MDT.

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 Saudi Augtyro case we build the document pack, coordinate the kingdom-side oncology referral and the SFDA NPP application, 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.

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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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