Augtyro

United Arab Emirates · access guide

How to access Augtyro for ROS1-positive non-small-cell lung cancer and NTRK-positive solid tumours from the UAE: 2026 pathway via UAE medical oncology and named-patient supply

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

The UAE has built one of the deepest medical oncology and molecular diagnostics networks in the wider region. Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, Burjeel Medical City, American Hospital Dubai, Mediclinic City Hospital, and King's College Hospital London Dubai all run thoracic, medical, and where relevant paediatric oncology services that diagnose, biomarker-test, and treat solid tumours driven by rare molecular drivers. Augtyro (repotrectinib) is a recent Bristol Myers Squibb next-generation tyrosine kinase inhibitor that covers 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. Given that the FDA approved the ROS1 indication in November 2023 and expanded the label to NTRK fusions in June 2024, the UAE supply route in 2026 most commonly runs through the named-patient programme (NPP) pathway rather than through a fully registered commercial channel. For a UAE patient with newly diagnosed ROS1-positive metastatic NSCLC, or for any UAE patient with an NTRK-fusion-positive solid tumour for whom Augtyro is the chosen treatment, the operational question is which prescribing centre fits the case, how the molecular diagnostic confirmation and the NPP application get done in parallel, what the realistic financial exposure looks like, and how the long-term refill cycle settles in.

This page explains how the pathway works in 2026 for a UAE-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 AED, what to monitor on therapy (dizziness in the first 14 days, liver enzymes, blood counts, glucose, lipids, neurology symptoms, the less common but real risk of pneumonitis), and how the treatment plan settles into a UAE family's life. It is concierge documentation written for a family already in conversation with a treating medical oncologist or paediatric oncologist and wants the operational reality laid out plainly.

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. The FDA approved Augtyro in November 2023 for ROS1-positive locally advanced or metastatic NSCLC in adults, covering both the TKI-naive and post-crizotinib settings. The FDA expanded the label in June 2024 to NTRK gene fusion-positive solid tumours in adults and in paediatric patients age 12 years and older. Both approvals were based on the TRIDENT-1 trial.

For a UAE 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 UAE patient with ROS1-positive NSCLC who has progressed on crizotinib or another first-generation ROS1 TKI, the TRIDENT-1 post-crizotinib cohort showed an objective response rate of 38 percent, with activity retained in patients carrying the ROS1 G2032R solvent-front resistance mutation that limits crizotinib and entrectinib. For a UAE patient with an NTRK-fusion-positive solid tumour, TRIDENT-1 showed an objective response rate of 58 percent in TKI-naive patients and 50 percent in TKI-pretreated patients, with responses across NTRK1, NTRK2, and NTRK3 fusions and across multiple tumour histologies (thyroid, sarcoma, salivary gland, NSCLC, colorectal). These are the data the UAE oncology team will anchor on.

What Augtyro is, in plain language

Augtyro is an oral capsule. The dosing schedule is unusual and matters for the patient education conversation:

- **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 principally about managing initial dizziness. Dizziness is the dose-limiting toxicity for many patients in the first 1 to 2 weeks; the lead-in allows tolerance to develop before escalating to the full maintenance dose. Most patients should expect some dizziness in the first week or two that improves with continued dosing. Patients who feel unable to drive or operate machinery during the lead-in should not do so, and a family member or driver supporting the patient through the first two weeks is part of the practical handoff.

Storage is room temperature; no refrigeration is required. There is no infusion, no inpatient stay, no certified-centre requirement. After the prescribing oncologist writes the first prescription and the dispensing pharmacy fills it, the patient takes Augtyro at home, returns for monitoring labs and a clinical visit at the end of the lead-in, and then settles into a monthly refill cycle with periodic neurology, glucose, and liver-enzyme review.

For metastatic disease, treatment continues until the disease progresses or the patient does not tolerate the medication.

The mechanism, in clinical shorthand: ROS1 rearrangement or NTRK gene fusion produces a constitutively active fusion kinase that drives malignant transformation. Augtyro is a macrocyclic next-generation TKI; the closed-ring scaffold constrains binding-mode flexibility and confers activity against the solvent-front resistance mutations (ROS1 G2032R, TRKA G595R, TRKB G639R, TRKC G623R) that emerge on first-generation inhibitors. Augtyro is also CNS-penetrant, with intracranial response rates that match or exceed the systemic response rates.

The biomarker requirement: confirmed ROS1 or NTRK fusion

Augtyro is a targeted therapy. It does not work in patients without a documented ROS1 rearrangement or NTRK fusion, and prescribing it without confirmed biomarker positivity is not appropriate. The eligibility gate is molecular diagnostic confirmation.

For the **ROS1-positive NSCLC indication**, ROS1 rearrangement is detected by one or more of:

- **Immunohistochemistry (IHC)** as a rapid screen, with confirmatory FISH or NGS for borderline or positive cases. - **Fluorescence in situ hybridisation (FISH)**: detects ROS1 break-apart rearrangements regardless of fusion partner. - **Next-generation sequencing (NGS)**, on tumour tissue or on circulating tumour DNA. NGS identifies the ROS1 rearrangement plus the specific fusion partner (CD74-ROS1, EZR-ROS1, and SDC4-ROS1 are the most common), co-occurring driver mutations, and resistance mutations at progression. NGS is increasingly the preferred primary test in UAE oncology practice.

For the **NTRK fusion-positive solid tumour indication**, NTRK1, NTRK2, or NTRK3 fusion is detected by:

- **NGS** as the preferred test (DNA-based and RNA-based panels both have a role; RNA-based fusion assays are particularly sensitive for NTRK fusions because the breakpoints in NTRK genes can be diverse). - **IHC pan-TRK** as a useful screen, particularly in tumour types with higher prior probability of NTRK fusion (mammary analogue secretory carcinoma of salivary gland, infantile fibrosarcoma); positive IHC requires confirmation by NGS or RNA-based fusion assay.

UAE-side molecular diagnostic capability sits at the prescribing centres' own pathology departments (Cleveland Clinic Abu Dhabi pathology, SSMC pathology, the Mediclinic Middle East lab network) and at regional and international reference laboratories (Caris Life Sciences, Foundation Medicine) for comprehensive NGS panels and complex liquid biopsy work. If the original diagnostic biopsy did not include ROS1 or NTRK testing, the conversation often starts with submission of archived tissue to a reference lab or with re-biopsy. This is normal in 2026 and not a process delay.

The named-patient supply pathway in the UAE

Augtyro is a recent FDA-approved oncology drug. As of mid-2026, the Emirates Drug Establishment (EDE) registration status is most likely pending or not yet completed in the standard commercial channel. [VERIFY: current EDE registration status]. The UAE supply route in 2026 therefore most commonly runs through the named-patient programme pathway:

1. The prescribing oncologist documents the biomarker-confirmed indication and the clinical rationale for Augtyro versus the available alternatives (entrectinib, crizotinib, larotrectinib, or chemotherapy depending on tumour type and prior treatment). 2. The prescribing centre's regulatory office files the named-patient request with EDE, including the molecular pathology report, the imaging and staging documentation, the prior treatment history, and the MDT recommendation. 3. The Bristol Myers Squibb regional office coordinates the supply, typically through Cigalah, Gulf Pharmaceutical Industries, or another regional distributor working with BMS oncology products. 4. Once EDE approves the named-patient application, the prescribing centre's pharmacy fills the first 30-day supply.

This is not unusual for recent FDA-approved oncology drugs in the UAE. The MENA regulatory environment has matured to handle named-patient access for biomarker-defined indications, and the UAE in particular has a well-established pathway. Typical turnaround from MDT recommendation through EDE NPP approval to first dispense is 4 to 10 weeks for a complete file.

Eligibility at a UAE oncologist's clinic

For UAE-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 the ROS1-positive indication, NSCLC (predominantly adenocarcinoma; squamous histology with ROS1 rearrangement is uncommon but possible). For the NTRK-positive indication, any solid tumour where the NTRK fusion is documented as the molecular driver. 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 chest/abdomen/pelvis, PET-CT, and brain MRI. 4. For NTRK-positive solid tumours: locally advanced or metastatic disease per the underlying tumour-type staging framework. 5. For the paediatric NTRK indication: age 12 years and older with the relevant solid tumour and confirmed NTRK fusion. 6. Baseline laboratory workup: complete blood count, comprehensive metabolic panel including liver function tests and bilirubin, fasting glucose and HbA1c, lipid panel, uric acid. 7. Baseline ECG with QTc and heart-rate documentation. 8. Baseline neurological examination: cognitive baseline, gait and coordination assessment, sensory examination. Augtyro has a recognised neurotoxicity profile (dizziness, paraesthesia, taste alteration, possible cognitive disturbance or mood change). Baseline characterisation matters for later attribution. 9. Baseline pulmonary assessment. 10. Pregnancy and lactation screen. Augtyro is contraindicated in pregnancy. Effective contraception is required for women of reproductive potential during treatment and for two months after the last dose. Lactation is contraindicated during treatment and for ten days after the last dose. Male partners with female partners of reproductive potential are advised to use effective contraception. For paediatric patients age 12 and older of reproductive potential, the counselling conversation is handled within the standard paediatric oncology framework. 11. Drug interaction screen for current medications and herbal products. Strong CYP3A4 inhibitors (clarithromycin, ketoconazole, ritonavir) and strong inducers (rifampin, phenytoin, St John's wort) alter repotrectinib exposure. Grapefruit and grapefruit juice are avoided.

A UAE patient should arrive at the oncology conversation with the most recent diagnostic workup: pathology report with histology and biomarker results, contrast CT or PET-CT imaging, brain MRI where relevant, and the full treatment history with response and tolerability data if any prior systemic therapy has been given. Reserve Meds organises this documentation pack so the oncology team can confirm eligibility on the first review and start the NPP application in parallel with the clinical workup.

The UAE prescribing and dispense picture, plainly

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

- Cleveland Clinic Abu Dhabi, with a comprehensive medical and thoracic oncology service and an active molecular tumour board that reviews ROS1-positive and NTRK-positive cases. - Sheikh Shakhbout Medical City, with a medical oncology service and MD Anderson Cancer Center affiliation. - Burjeel Medical City, with an oncology programme that handles biomarker-driven NSCLC and rare-tumour cases. - American Hospital Dubai oncology. - Mediclinic City Hospital comprehensive cancer centre. - King's College Hospital London Dubai.

For the paediatric NTRK indication in patients age 12 and older, the relevant UAE paediatric oncology centres are Sheikh Khalifa Medical City paediatric haematology-oncology, Tawam Hospital paediatric oncology, and the relevant private-sector paediatric oncology services. The paediatric pathway runs parallel to the adult pathway with paediatric-specific MDT review and counselling.

The pathway:

1. **Diagnosis and molecular confirmation**: typically done at the diagnosing centre's pathology lab or sent to a regional or international reference lab for comprehensive NGS. Turnaround is 2 to 4 weeks for NGS in most UAE settings. 2. **Multidisciplinary tumour board review**: thoracic or 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. Documentation of rationale and treatment plan. 3. **Named-patient application**: prescribing centre's regulatory office files with EDE. BMS regional office coordinates supply. 4 to 10 weeks for a complete file. 4. **Insurance pre-authorisation**: UAE private insurers (AXA Gulf, NEXtCARE, MSH, Bupa Global, Allianz Care) handle Augtyro on a case-by-case basis given NPP status. Daman and Thiqa for Emirati nationals follow institutional pathways. Documentation requirement includes biomarker confirmation, MDT recommendation, NPP approval, and a clinical rationale letter. 5. **Pharmacy dispense**: the prescribing centre's pharmacy or a partnered specialty pharmacy fills the first 30-day supply. Counselling at first dispense covers the 14-day lead-in, the dizziness-tolerance trajectory, the food requirement, the grapefruit avoidance, and the neurology symptom watch. 6. **Refill cycle**: monthly thereafter, with continued monitoring lab documentation.

Cost expectation in AED

US list price (2026) for Augtyro at the standard 160 mg twice-daily maintenance dose is approximately USD 25,000 to USD 30,000 per 30-day supply, with an annual cost of approximately USD 300,000 to USD 360,000. The price band sits above alectinib and brigatinib due to the dual ROS1 plus NTRK indication and the limited competition in the post-crizotinib ROS1 and pretreated NTRK settings.

At indicative 2026 cross rates, a single 30-day supply at USD 27,500 is approximately AED 101,000, and the annual cost at USD 330,000 is approximately AED 1.21 million. A multi-year treatment course on Augtyro accumulates accordingly.

Total cost of care additions include the oncologist's consultation fees, monitoring laboratory fees (every 2 to 4 weeks for the first 3 months then monthly to quarterly), imaging fees (contrast CT or PET-CT every 8 to 12 weeks, brain MRI every 12 weeks if CNS metastases at baseline), and supportive care including endocrinology input for hyperglycaemia where it develops and neurology input for symptoms during the lead-in or later treatment. These add 5 to 15 percent to the drug cost base in UAE private-sector settings.

Thiqa coverage for Emirati nationals has historically extended to oncology medications on the SFDA and EDE approved-drug formulary; for an NPP-pathway drug, the pre-authorisation conversation runs through the prescribing centre's insurance liaison alongside the regulatory office. Bristol Myers Squibb regional access programmes may underwrite portions of the cost for specific patient cohorts during the NPP phase; confirm eligibility at intake.

Monitoring on therapy

The monitoring schedule for Augtyro is structured around the principal toxicities, which include a distinct neurology profile compared with alectinib or brigatinib:

- **Neurological examination**: monthly for the first 3 months, then quarterly or symptom-driven. Dizziness is dose-limiting for many patients in the first 1 to 2 weeks. Paraesthesia (sensory neurotoxicity) is recognised. Dysgeusia (taste alteration) is common. Cognitive disturbance or mood change at any point during treatment warrants dose reduction and neurology input. - **Liver function tests**: every 2 to 4 weeks for the first 3 months, then monthly to quarterly. AST and ALT elevations require dose interruption per protocol at grade 3 or higher. - **Complete blood count**: every 2 to 4 weeks for the first 3 months, then monthly. Anaemia is the most common haematological adverse event. - **Fasting glucose and HbA1c**: monthly for the first 3 months, then quarterly. Hyperglycaemia is recognised; new-onset or worsening diabetes requires endocrinology input. - **Lipid panel**: baseline and every 3 to 6 months. - **Uric acid**: baseline and as clinically indicated. - **ECG**: as clinically indicated. - **Pulmonary symptoms**: any new or worsening dyspnoea, cough, or fever triggers HRCT and pulmonology input to evaluate for pneumonitis or interstitial lung disease. Pulmonary AEs on Augtyro are less common than on brigatinib but real. - **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. There is no animal-source material in standard manufacturing, 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 already endorses the treatment shape.

The family-logistics burden of Augtyro sits in three places: the 14-day lead-in (with the dizziness signal and the driver-support implication), the chronic twice-daily dosing schedule (160 mg morning and evening with food, for as long as the disease responds), and the multi-pillar monitoring routine (neurology, hepatology, haematology, endocrinology, lipids). The first 30 to 60 days are the operational pivot; once the patient has cleared the lead-in and the first month of maintenance dosing, the rhythm settles. Adherence support (medication diary, smartphone reminders, family member co-monitoring) is part of the practical handoff at first refill.

For working patients, the schedule is manageable once the lead-in is past. The capsules are taken with breakfast and dinner. Monitoring lab visits cluster around standard workweek patterns. The neurology examinations are typically brief and can be coordinated with the routine oncology visits.

For paediatric patients age 12 and older with NTRK-positive disease, the operational logistics involve the parent or guardian alongside the patient. Adolescent-specific counselling on adherence, contraception where relevant, and symptom reporting is part of the paediatric oncology service handoff.

When Augtyro is not the right call

Augtyro is the right answer for confirmed ROS1-positive NSCLC in adults and for confirmed NTRK fusion-positive solid tumours in adults and paediatric patients age 12 and older. It is not the right answer for:

- ROS1-negative and NTRK-negative disease. The biomarker gate is non-negotiable. Patients without documented biomarker positivity route to other targeted therapies, immune checkpoint inhibitors, or standard chemotherapy depending on tumour type, stage, and biomarker profile. - Patients with a history of clinically significant interstitial lung disease where the pneumonitis risk on Augtyro makes the risk-benefit unfavourable. - Patients with severe pre-existing cognitive impairment or with concurrent neurotoxic agents where the additive neurology risk on Augtyro is unacceptable. - Patients with uncontrolled hyperglycaemia until the metabolic profile is stabilised. - Pregnancy. Effective contraception is required during treatment and for two months after the last dose.

For confirmed ROS1-positive NSCLC where Augtyro is not the chosen option, the alternatives in 2026 are entrectinib (first-generation ROS1 / NTRK inhibitor with CNS activity, less robust against G2032R), crizotinib (first-generation ROS1 TKI, historical standard, less CNS-penetrant), and standard platinum-doublet chemotherapy. For confirmed NTRK-positive solid tumours where Augtyro is not the chosen option, the alternatives are larotrectinib (first-generation TRK-selective inhibitor) and entrectinib. The clinical conversation with the treating oncologist about which TKI to start is real and worth having; this page describes Augtyro because that is the medication you have asked about.

Reserve Meds does not push a default. If the conversation with the treating oncologist points toward entrectinib or larotrectinib, the operational pathway shifts accordingly and we coordinate that pathway instead. Reserve Meds does not promote one ROS1 or NTRK inhibitor over another. The decision is the treating oncologist's and the multidisciplinary tumour board's.

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 UAE Augtyro case we build the document pack (pathology report, molecular diagnostic results, imaging, prior treatment history, oncologist clinical rationale letter, MDT recommendation), submit first-review requests to the chosen prescribing centre, support the EDE named-patient application alongside the prescribing centre's regulatory office, coordinate the insurance pre-authorisation conversation, set up the first 30-day dispense at the chosen pharmacy, and stay with the case through the refill cycle for as long as the family wants concierge support. 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.

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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