Alyftrek access in the UAE: the MOHAP and EDE named-patient pathway

How patients in the United Arab Emirates access Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) for cystic fibrosis when the medicine is not yet locally registered.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

1. Quick orientation

Alyftrek is the brand name for vanzacaftor/tezacaftor/deutivacaftor, a next-in-class oral once-daily fixed-dose triple combination cystic fibrosis transmembrane conductance regulator (CFTR) modulator developed by Vertex Pharmaceuticals. The US Food and Drug Administration approved Alyftrek on 20 December 2024 for patients aged six years and older with at least one F508del mutation or one of approximately 94 other responsive CFTR mutations. The Alyftrek label covers approximately 31 additional non-F508del mutations not included on the Trikafta label, expanding the eligible CF population. UAE MOHAP and the Emirates Drug Establishment (EDE) have not yet completed national registration of Alyftrek. UAE CF patients who meet the FDA genotype eligibility, or who are transitioning from Trikafta, reach Alyftrek through the federal unregistered-medicine import permit administered by MOHAP and, from 29 December 2025, through the EDE portal at ede.gov.ae. Reserved for you.

2. Why UAE patients need Alyftrek via the named-patient pathway

The UAE pharmaceutical regulatory framework recognises three structural access gaps: registered but not stocked at a particular hospital pharmacy, registered for one indication but prescribed for another FDA-approved indication, and not registered locally at all. Alyftrek is the third pattern. Vertex is the originator of the entire approved CFTR modulator class (Kalydeco, Orkambi, Symdeko, Trikafta, and Alyftrek) and remains the sole commercial supplier of CFTR modulator therapy worldwide. The UK MHRA approved Alyftrek in March 2025 and NHS England has subsequently moved Alyftrek into commissioned access. The European Commission granted EU marketing authorisation on 1 July 2025 across all 27 EU member states plus Iceland, Liechtenstein, and Norway. UAE MOHAP and EDE have not yet completed national review and routine commercial stocking as of the date of this page.

Three patient patterns drive Alyftrek demand through the UAE named-patient pathway. First, eligibility expansion. Patients carrying one of the approximately 31 responsive CFTR mutations covered by the Alyftrek label but not the Trikafta label have a label-supported option for the first time. Where the patient's previous CFTR genotype reading excluded them from Trikafta, Alyftrek may be the first highly effective modulator they qualify for. Second, switch demand. Patients already established on Trikafta who would benefit from once-daily simpler dosing (pediatric families, adolescents, adults with adherence challenges) sometimes elect to pursue Alyftrek. Third, second-opinion and expatriate patients. Patients seen at international CF expert centres or expatriate families resident in the UAE who elect to source US-origin product directly through cash-pay specialty coordination.

In all three patterns, the EDE unregistered-medicine import permit is the recognised regulatory route.

3. The MOHAP and EDE named-patient pathway for Alyftrek

The federal pathway for a UAE-licensed physician to obtain Alyftrek is the unregistered-medicine import permit, historically administered by MOHAP and, from 29 December 2025, through the EDE portal under Federal Decree-Law No. 38 of 2024. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a

specific patient when the medicine is approved by a recognised reference authority (the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. The Alyftrek case is straightforward: there is no locally registered next-in-class CFTR modulator in the UAE, and for the approximately 31 responsive mutations covered by Alyftrek but not Trikafta, no alternative CFTR modulator is even FDA-approved.

A complete application typically includes:

- A clinical justification letter from the treating CF specialist (paediatric or adult pulmonologist) naming Alyftrek and the indication
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location)
- An anonymised patient identifier where the EDE submission allows
- The patient's CFTR genotype report, confirming at least one F508del mutation or one of the approximately 94 other Alyftrek-responsive mutations on the FDA label table
- Full product details: Alyftrek, vanzacaftor/tezacaftor/deutivacaftor, weight-banded tablet strength per the label table, Vertex Pharmaceuticals, typical 28-day pack quantity
- The destination dispensing hospital outpatient pharmacy name, license number, and pharmacy in charge
- A chain-of-custody plan describing how the ambient-stable tablets will move from the US specialty pharmacy through the importer to the dispensing pharmacy

The clinical-justification angle that matters most for Alyftrek is genotype confirmation. The treating CF specialist documents the CFTR genotype on the patient's genetic report, the matched Alyftrek-responsive mutation on the FDA label table, and the rationale for the choice of Alyftrek versus Trikafta where both are options. For patients with non-F508del responsive mutations covered only by the Alyftrek label, the rationale is automatic. For switch cases from Trikafta, the rationale is once-daily simplification or other clinician-judged benefit.

Approval timelines for routine UAE cases are typically 5 to 15 business days. First import of Alyftrek into a given hospital pharmacy may extend toward the upper end of that range.

4. Where Alyftrek gets dispensed in the UAE

Alyftrek is an oral CFTR modulator. It does not require infusion infrastructure, cold-chain storage, or specialised dispensing equipment. The dispensing requirement is a UAE-licensed hospital outpatient pharmacy or specialised import pharmacy, paired with a UAE-licensed paediatric pulmonologist, adult pulmonologist, or CF specialist supervising the case. Because Alyftrek requires liver function testing and ophthalmologic examinations on a defined schedule, the dispensing facility is paired with the patient's continuing CF clinic where laboratory and ophthalmology services are available.

UAE institutions with paediatric and adult pulmonology services and named-patient import infrastructure include Cleveland Clinic Abu Dhabi (M42 group, Al Maryah Island, with adult multispecialty services and pharmacy accredited by the American Society of Health-System Pharmacists), Sheikh Khalifa Medical City (SKMC, SEHA network, JCI-accredited, with cardiology, oncology, and paediatric subspecialty services), Tawam Hospital in Al Ain (SEHA network), American Hospital Dubai (Mayo Clinic Care Network member, with paediatric oncology and broader paediatric services), King's College Hospital London Dubai, Mediclinic City Hospital in Dubai Healthcare City, and the larger NMC Healthcare flagship sites. For families resident in the Northern Emirates without a local CF specialist centre, the typical pattern is to route to Dubai or Abu Dhabi where the patient's treating physician holds joint privileges or where the case is co-managed with a UAE-licensed paediatric pulmonologist.

5. Real cost picture for Alyftrek in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. Three line items frame the case economics.

First, drug cost. Vertex set the US wholesale acquisition cost for Alyftrek at approximately USD 370,269 per patient per year at launch, equivalent to approximately USD 28,404 per 28-day pack. This is approximately 7 percent above the

published WAC for Trikafta (approximately USD 346,048 per year). For a UAE cash-pay course, a 28-day pack translates to approximately AED 104,000, and the annual course to approximately AED 1.36M before any rebates or US patient support, which are not portable to international patients. Vertex GPS, copay assistance, and free-drug bridging are US-only programmes.

Second, international logistics. Alyftrek is a small-molecule tablet stored at controlled room temperature, with conventional pharmaceutical-grade stability. International logistics for an ambient DSCSA-compliant shipment to the UAE typically runs USD 400 to USD 1,500 (approximately AED 1,500 to AED 5,500) depending on destination emirate and urgency window. Because the regimen is chronic, the operational pattern is repeat 28-day shipments planned from the first case rather than one-off procurement.

Third, regulatory and coordination. UAE customs and EDE permit fees are nominal relative to the drug cost. On the insurance side, Daman National Health Insurance (operator of Thiqa for UAE nationals in Abu Dhabi), GIG Gulf, Sukoon Insurance, ADNIC, and Orient Insurance each assess named-patient imports for rare-disease therapies case by case. CF is a recognised rare disease and several UAE insurers maintain rare-disease assessment frameworks; pre-authorisation is the typical pattern. Cash-pay is the default posture.

6. Typical timeline for Alyftrek in the UAE

The EDE timeline for routine unregistered-medicine permits is typically 5 to 15 business days. Alyftrek is ambient-stable, which removes the cold-chain transit window. End-to-end, a typical Alyftrek case in the UAE runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds, with CFTR genotype review against the Alyftrek FDA label table at this step; 3 to 7 days for the treating CF specialist and dispensing hospital pharmacy or specialty importer to assemble the application and genotype documentation; 5 to 15 business days for EDE review (longer for first import into a given facility); 3 to 5 days for US sourcing through Vertex's contracted specialty pharmacy network, release documentation, and ambient courier shipment; 1 to 2 days for UAE customs clearance under the permit; and final verification and dispense at the hospital outpatient pharmacy. Because Alyftrek is chronic, repeat-shipment cadence is planned from the first case, with weight-banded pediatric dose-step checkpoints scheduled at the case-acceptance stage rather than treated as one-off changes.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the EDE application. The treating UAE CF specialist documents the patient's diagnosis of cystic fibrosis, the CFTR genotype on the patient's genetic report, the matched Alyftrek-responsive mutation on the FDA label table, the patient's age and weight to confirm Alyftrek eligibility (six years and older) and the correct weight-banded tablet strength, prior therapy history (background CF care including airway clearance, mucolytics, inhaled antibiotics, pancreatic enzyme replacement, nutritional support, and any prior CFTR modulator therapy such as Trikafta), the rationale for selecting Alyftrek (eligibility expansion for non-F508del responsive mutations, or once-daily simplification for switch cases), the planned dosing regimen (oral, once daily, with fat-containing food, weight-banded tablet strength per the label table, chronic indefinite duration), and the monitoring plan, with particular emphasis on the boxed warning for serious and potentially fatal drug-induced liver injury and liver failure (liver function tests at baseline, every three months during the first year of treatment, and annually thereafter), baseline and follow-up ophthalmologic examinations for cataracts in pediatric patients (class effect across CFTR modulators), and concomitant medication review for CYP3A interactions including strong and moderate inhibitors and inducers (hormonal contraceptives, certain antifungals, antibiotics, anticonvulsants, and herbal products such as St. John's wort) at initiation and at every regimen change.

The letter is co-filed with the physician's UAE license verification, the dispensing facility license number, the requested pack and quantity (typical 28-day pack), and the chain-of-custody plan for the ambient shipment.

8. Common questions about Alyftrek in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Alyftrek? Each insurer assesses named-patient imports for rare-disease therapies case by case. Thiqa, the government-funded programme for UAE nationals administered by Daman, has rare-disease coverage frameworks; private insurers vary. CF is a recognised rare disease, and pre-authorisation is the typical pattern. We do not promise coverage from any insurer.

Will my paediatric pulmonologist's DHA or DOH license be sufficient? Yes. Any UAE-licensed paediatric pulmonologist or adult pulmonologist with CF expertise practising in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter.

Is CFTR genotype testing available in the UAE? Yes. Major UAE genetics services run CFTR genotype testing on certified next-generation sequencing platforms. Where a UAE patient has had testing at a US, UK, or other reference laboratory, that genetic report is accepted in the EDE filing.

What is the safety profile I should know about? Alyftrek carries a boxed warning for serious and potentially fatal drug-induced liver injury and liver failure. Warnings and precautions in the label include hypersensitivity reactions, drug interactions via CYP3A, and cataracts in pediatric patients (a class effect observed across CFTR modulators). The most common adverse reactions reported in the SKYLINE 102 and SKYLINE 103 trials were generally consistent with the Trikafta safety profile, with no new class-level signals. Liver function tests are obtained at baseline, every three months during the first year, and annually thereafter.

Why Alyftrek versus Trikafta? Alyftrek is once-daily; Trikafta is twice-daily. Alyftrek covers approximately 31 additional CFTR mutations on the label. In the SKYLINE 102 and 103 trials, Alyftrek was non-inferior to Trikafta on the primary endpoint of percent predicted FEV1 through week 24, and superior on the secondary endpoint of sweat chloride reduction. The therapeutic choice rests with the treating CF specialist.

Can a paediatric patient receive Alyftrek? Yes, for patients aged six years and older meeting the genotype eligibility on the FDA label table. The treating clinician selects the correct tablet strength from the label table based on age and weight at initiation, and rechecks dosing as the patient grows. Reserve Meds plans repeat-shipment cadence and pediatric dose-step checkpoints at the case-acceptance stage.

9. Where Reserve Meds fits in Alyftrek cases

Reserve Meds is a US-based concierge coordinator. We do not replace your CF specialist, the EDE, the dispensing hospital pharmacy, or your insurer. What we do for an Alyftrek case is verify eligibility within 24 to 48 hours, with CFTR genotype review against the Alyftrek FDA label table at the intake stage; supply your physician's team with a documentation kit referencing the Vertex prescribing information, weight-banded dosing, LFT monitoring schedule, and CYP3A interaction list; align US-side sourcing through Vertex's contracted specialty pharmacy network under DSCSA-compliant chain-of-custody and serialisation; coordinate the ambient courier shipment under chain-of-custody documentation; and provide a single named coordinator across the case, with pediatric dose-step checkpoints planned at the case-acceptance stage. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your UAE CF specialist has confirmed CFTR genotype eligibility on the FDA label table and recommends Alyftrek, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

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Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

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