Alyftrek access in Saudi Arabia: the SFDA Personal Importation Program

How patients in the Kingdom of Saudi Arabia access Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) for cystic fibrosis in patients aged 6 years and older.

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 once-daily oral triple combination cystic fibrosis transmembrane conductance regulator (CFTR) modulator developed, manufactured, and commercialised by Vertex Pharmaceuticals. The US Food and Drug Administration approved Alyftrek on December 20, 2024 for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation or one of approximately 94 other responsive mutations in the CFTR gene. The label covers roughly 31 additional non-F508del mutations not included on the Trikafta label, which expands the population of CF patients now eligible for highly effective CFTR modulator therapy. UK MHRA approval followed in March 2025 and the European Commission granted EU marketing authorisation on July 1, 2025. In the Kingdom of Saudi Arabia, the Saudi Food and Drug Authority (SFDA) has not yet completed national review for Alyftrek and the product is not in routine commercial stocking. Saudi CF patients whose treating specialist has confirmed a label-eligible genotype reach Alyftrek through the SFDA Personal Importation Program (PIP). Reserved for you.

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

Three patterns of access gap apply across the Kingdom: a drug is registered with SFDA but not stocked at the treating hospital on the day the patient needs it; a drug is registered with SFDA for one indication but the physician is prescribing it for a different FDA-approved indication that has not been added to the local label; or a drug is FDA-approved but the manufacturer has not yet completed SFDA registration. Alyftrek sits squarely in the third pattern. The product is a recently launched CFTR modulator with US commercial launch in January 2025 and UK MHRA and EU approvals through 2025. SFDA has not yet completed national review, and the product is not in routine commercial stocking in the Kingdom.

Three named-patient demand patterns repeat in the Kingdom's CF specialty community. First, eligibility expansion: the Alyftrek label covers approximately 31 CFTR mutations not covered by the Trikafta label, so patients who were previously ineligible for any CFTR modulator now have a label-supported option. Where SFDA review is incomplete, the PIP is the only available route. 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 through the PIP. Third, second-opinion and expatriate cases: patients seen at international CF expert centres and expatriate families resident in the Kingdom who elect to source US-origin product directly through cash-pay specialty coordination.

The clinical setting reinforces the route. CF is a lifelong genetic disease, CFTR modulator therapy fundamentally changes its trajectory for eligible patients, and Vertex remains the sole commercial supplier of the entire CFTR modulator class globally. There is no non-Vertex competitor in the class as of this page's review date. Saudi Vision 2030's investment in rare-disease care and pediatric subspecialty programs surfaces newly diagnosed CF patients with genotypes that match the expanded Alyftrek label, which is exactly the population the named-patient framework is designed to serve.

3. The SFDA Personal Importation Program for Alyftrek

The SFDA Personal Importation Program allows a Kingdom-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable for the patient. The framework explicitly contemplates pediatric specialty therapies and rare-disease modulators of this class. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, with named-patient activity increasingly routed through the Ghad digital platform alongside the agency's English portal at sfda.gov.sa.

A complete PIP application for Alyftrek includes the clinical justification letter from the treating CF specialist (typically a pediatric or adult pulmonologist with CF expertise); the treating physician's licensing verification through the Saudi Commission for Health Specialties (SCFHS) in pulmonology, pediatric pulmonology, or relevant specialty; the patient identifier in the format SFDA requires for the named-patient case file; full product details (Alyftrek, vanzacaftor/tezacaftor/deutivacaftor, Vertex Pharmaceuticals, the appropriate weight-banded tablet strength per the FDA label, 28-day pack, requested quantity including refill plan); the destination dispensing facility license; and a chain-of-custody plan for ambient shipment from the US point of release through international transit to the receiving Saudi pharmacy.

The clinical-justification angle for Alyftrek turns on genotype confirmation. The treating specialist documents the patient's CFTR genotype with explicit reference to the testing platform and the laboratory, confirms that the genotype is on the FDA label table (at least one F508del mutation or one of the responsive mutations including the approximately 31 non-Trikafta mutations now covered), confirms the patient is aged 6 years or older, and documents the rationale (initiation on first-line CFTR modulator therapy for newly eligible genotypes; switch from Trikafta to once-daily dosing for adherence or simplification; or initiation in an expatriate or second-opinion case). Weight-banded tablet strength selection from the label table is documented at initiation, with a planned check at pediatric dose-step thresholds as the patient grows. Approval timelines for routine SFDA cases run 10 to 21 business days; complex first-import CFTR modulator cases into a given institution can extend to 6 to 10 weeks.

4. Where Alyftrek gets dispensed in Saudi Arabia

Alyftrek is a room-temperature small-molecule oral tablet, supplied in two strengths for weight-banded pediatric and adult dosing, packaged in a 28-day commercial unit. There is no cold chain, no reconstitution step, and no infusion infrastructure required. The dispensing requirement is therefore an SFDA-licensed hospital outpatient pharmacy or specialty import pharmacy aligned with a CF specialist service capable of CFTR modulator monitoring (liver function tests, ophthalmologic exams in pediatric patients, CYP3A drug-interaction review).

Kingdom institutions with adult and pediatric CF or rare-pulmonology services that handle named-patient imports as routine workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah, with its tertiary pediatric pulmonology and genomics programs and experienced in-house import pharmacy; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network; King Saud University Medical City (KSUMC) with pediatric pulmonology programs; Dr. Sulaiman Al Habib Medical Group (HMG), the largest private hospital network in the Kingdom with multiple facilities and routine PIP activity; Saudi German Hospital; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. For families whose treating CF specialist is at a smaller hospital, the practical route is to partner with an SFDA-licensed specialty importer based in Riyadh or Jeddah that handles the PIP filing while the institution's pulmonology service retains clinical responsibility.

5. Real cost picture for Alyftrek in Saudi Arabia

The Saudi riyal is pegged at approximately 3.75 SAR to 1 USD, which makes the dollar-denominated US wholesale acquisition cost the principal driver of the case economics. Three line items frame the cost.

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 (roughly SAR 106,500 per 28-day pack and SAR

1,388,500 per annual course). This is approximately 7 percent above the published WAC for Trikafta (approximately USD 346,048 per year), positioning Alyftrek as a successor product at a modest list-price premium reflecting once-daily dosing and broader mutation coverage. Vertex GPS US patient services, copay assistance, and patient assistance programs are US-only and do not extend to international named-patient cases.

Second, international logistics. Alyftrek is room-temperature stable with standard pharmaceutical-grade ambient shipping, DSCSA-compliant serialisation, and tamper-evident packaging. International logistics for an ambient shipment to the Kingdom typically runs SAR 1,500 to SAR 3,750 (approximately USD 400 to USD 1,000) and does not require gel packs, dry ice, or active temperature loggers.

Third, regulatory and coordination. SFDA documentation handling fees and Reserve Meds' concierge fee are itemised separately. On the insurance side, Bupa Arabia, Tawuniya (The Company for Cooperative Insurance), and MedGulf Arabia handle named-patient imports case by case, with several requiring pre-authorisation. The Council of Cooperative Health Insurance (CCHI) governs plan structure. Cash-pay is the default operating posture for an indefinite-duration chronic therapy of this kind, with annual budgeting from the first case. Reserve Meds quotes an indicative range based on the initial intake, then a transparent firm quote with each line item shown separately.

6. Typical timeline for Alyftrek in Saudi Arabia

The SFDA timeline for routine PIP cases runs 10 to 21 business days. Alyftrek is an ambient oral tablet, so cold-chain transit time does not apply. End-to-end, a typical Alyftrek case in the Kingdom runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 7 days for the treating CF specialist and the dispensing hospital's import pharmacy or an SFDA-licensed specialty importer to assemble the application with CFTR genotype documentation; 10 to 21 business days for SFDA review (longer for first-time CFTR modulator imports into the institution, where 6 to 10 weeks is plausible); 3 to 5 days for US sourcing through Vertex's contracted specialty pharmacy channel and qualified ambient shipment with full DSCSA-compliant chain-of-custody; 1 to 3 days for Saudi customs clearance under the PIP permit; and final receipt and release at the dispensing pharmacy. Because Alyftrek is dosed once daily on a chronic indefinite basis with weight-banded pediatric titration, Reserve Meds plans repeat-shipment cadence and pediatric dose-step checkpoints at the case-acceptance stage rather than treating each 28-day pack as a one-off.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA PIP application. The treating Kingdom CF specialist documents the patient's diagnosis of cystic fibrosis, with ICD-10 coding; states the CFTR genotype with explicit reference to the testing platform, the laboratory, the date of the result, and confirmation that the genotype is on the FDA-approved Alyftrek label table (at least one F508del mutation or one of the approximately 94 responsive mutations including the approximately 31 non-Trikafta mutations now covered); confirms the patient is aged 6 years or older; documents the clinical rationale (initiation for newly eligible genotype, switch from Trikafta to once-daily dosing for adherence or simplification, or initiation in an expatriate or second-opinion case); states the planned dosing regimen (oral, once daily, with fat-containing food, weight-banded tablet strength selected from the label table, no loading dose, chronic indefinite duration as long as the patient is benefiting and tolerating therapy under specialist supervision); and describes the monitoring plan with particular emphasis on the boxed warning for serious and potentially fatal drug-induced liver injury.

The monitoring stack includes baseline liver function tests (ALT, AST, total bilirubin) followed by every three months during the first year of treatment and annually thereafter, with label-defined thresholds for dose interruption or discontinuation; baseline and follow-up ophthalmologic examinations for cataracts in pediatric patients (class effect across CFTR modulators); a CYP3A drug-interaction review at initiation and at every regimen change (hormonal contraceptives, antifungals, antibiotics, anticonvulsants, and St. John's wort are the high-yield interactions); and counselling on taking the tablet with food containing fat to optimise bioavailability of all three components.

The letter is co-filed with the physician's SCFHS license verification, the institutional pharmacy license, the requested pack count and refill plan, and the chain-of-custody plan for the ambient shipment to the dispensing site. Post-import, the treating

physician and dispensing pharmacy commit to adverse-event reporting through the SFDA National Pharmacovigilance Center for the full course of therapy.

8. Common questions about Alyftrek in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Alyftrek? Each plan handles named-patient imports case by case. Some reimburse fully when the medicine appears on the insurer's formulary; others reimburse a percentage; many require pre-authorisation with the clinical justification letter attached. CFTR modulator coverage in the Kingdom is highly case-dependent given the chronic indefinite nature of therapy and the annual budget impact. Reserve Meds supplies the documentation that lets the insurer assess; the claim is yours or your hospital's to file. We do not promise coverage from any insurer.

Will my pediatric pulmonologist's letter be sufficient? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications. Private-sector pulmonologists at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Is CFTR genotype testing available in the Kingdom? Yes. KFSH&RC genomics services, KAMC genetics laboratories, and reference labs aligned with the larger private networks run CFTR mutation panels including next-generation sequencing that detects the full label-covered mutation set. The testing laboratory is identified in the PIP filing, and the report is part of the application package.

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 also 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. There is no REMS program for Alyftrek; the boxed warning is managed by the LFT monitoring schedule on the label.

Why this drug 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. Reserve Meds does not select therapy.

Can my child take Alyftrek? Patients aged 6 years and older with at least one F508del mutation or one of the responsive mutations on the FDA label are eligible. The treating clinician confirms genotype eligibility against the label table at initiation and selects the weight-banded tablet strength.

9. Where Reserve Meds fits in Alyftrek cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating CF specialist, SFDA, the dispensing hospital pharmacy or specialty importer, or your insurer. What we do for an Alyftrek case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the FDA prescribing information, the once-daily weight-banded dosing, the CFTR genotype framing, and the LFT and ophthalmologic monitoring stack; align US-side sourcing through Vertex's contracted specialty pharmacy channel under DSCSA-compliant chain-of-custody; coordinate ambient shipment with a qualified specialty 3PL; and provide a single named Patient Concierge Coordinator across repeat shipments, pediatric dose-step checkpoints, and chronic refill cadence. Because CFTR modulator therapy is sole-sourced globally by Vertex, indefinite in duration, and supply-chain-stable, the case complexity sits in regulatory documentation and chronic-cadence planning rather than in physical logistics. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Kingdom CF specialist has confirmed a label-eligible CFTR genotype and recommends Alyftrek, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

Last medically reviewed: 2026-05-12.