Alyftrek access in Pakistan: the DRAP Special Permission pathway

How patients in Pakistan 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 approximately 31 additional non-F508del mutations not included on the Trikafta label. UK MHRA approval followed in March 2025 and the European Commission granted EU marketing authorisation on July 1, 2025. Cystic fibrosis is less common in Pakistan than in Western Caucasian populations and CF awareness is concentrated at a small number of pediatric pulmonology centres, but confirmed CF patients with a label-eligible genotype reach Alyftrek through the Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import No Objection Certificate. Reserved for you.

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

Three patterns of access gap apply across Pakistan: a drug is on the DRAP register but the patient's hospital pharmacy does not have it on hand; a drug is registered for one indication but not in the strength or pack size required; or a drug is FDA-approved but the manufacturer has not yet completed DRAP registration. Alyftrek sits in the third pattern. The product is a recently launched CFTR modulator with US commercial launch in January 2025, UK MHRA approval in March 2025, and EU authorisation on July 1, 2025. DRAP has not yet completed national review for Alyftrek and the product is not in routine commercial stocking in Pakistan.

Three structural reasons drive Alyftrek to the named-patient channel for Pakistani patients. First, the underlying epidemiology. CF is rarer in South Asian populations than in Caucasian populations of European ancestry, but it is not absent, and the genotypes seen in Pakistani families include mutations newly covered by the Alyftrek label that were not covered by the Trikafta label. Eligibility expansion to approximately 31 additional CFTR mutations matters disproportionately in populations whose genotypes are under-represented in the older first-generation modulator labels. Second, sole-source supply. Vertex remains the sole commercial supplier of the entire approved CFTR modulator class globally (Kalydeco, Orkambi, Symdeko, Trikafta, Alyftrek). There is no non-Vertex competitor and there is no Pakistani generic alternative. Third, switch and second-opinion demand. Patients already established on Trikafta who would benefit from once-daily simpler dosing sometimes elect to pursue Alyftrek through the named-patient pathway, and Pakistani families with international relatives often surface Alyftrek through second-opinion consultations at expert CF centres in the UK, US, and EU.

3. The DRAP Special Permission pathway for Alyftrek

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section, with Drug Registration Board oversight for new product registration matters. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also known as the Personal Use Import No

Objection Certificate (NOC). The framework covers Personal Use Import by an individual patient on physician prescription and Special Permission for Import of Unregistered Therapeutic Goods by hospitals or institutions, filed through DRAP's Online Import and Export System (OIES) electronic portal.

A complete DRAP application for Alyftrek includes the clinical justification letter from the treating CF specialist (typically a pediatric pulmonologist or adult pulmonologist with CF expertise); the treating physician's PMDC license verification with specialist registration in pulmonology or pediatric pulmonology; the patient identifier (CNIC for adults, B-Form for minors which is the common case given the pediatric label, passport for foreign nationals); full product details (Alyftrek, vanzacaftor/tezacaftor/deutivacaftor, Vertex Pharmaceuticals, the weight-banded tablet strength per the FDA label, 28-day pack, requested quantity including refill plan for chronic indefinite therapy); the destination dispensing facility license; the manufacturer or authorised distributor letter; and a chain-of-custody plan for ambient shipment from the US source through international transit to the receiving Pakistani pharmacy.

The clinical justification angle for Alyftrek turns on three elements: CFTR genotype confirmation, age confirmation (≥6 years), and the boxed-warning monitoring plan. The treating specialist documents the patient's CFTR genotype with explicit reference to the testing platform and the laboratory (most Pakistani CF testing is performed at AKUH genomics services, SKMCH&RC molecular pathology, the Centre for Human Genetics in Lahore, or international reference laboratories), confirms the genotype is on the FDA-approved Alyftrek label table 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 a newly eligible genotype, switch from Trikafta to once-daily dosing, or initiation in a 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. Routine DRAP personal-use cases typically clear in four to eight weeks; complex first-import CFTR modulator cases into a Pakistani institution can extend to ten to sixteen weeks.

4. Where Alyftrek gets dispensed in Pakistan

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 a DRAP-licensed hospital outpatient pharmacy or specialty import pharmacy aligned with a CF specialist service capable of CFTR modulator monitoring (liver function tests, ophthalmologic examinations in pediatric patients, CYP3A drug-interaction review).

Pakistani institutions with adult or pediatric CF expertise that handle named-patient imports as routine workflow include Aga Khan University Hospital (AKUH) in Karachi, with pediatric pulmonology and genomics services and a 24/7 pharmacy network; Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore for genotype testing infrastructure; the Children's Hospital and Institute of Child Health in Lahore, a major pediatric tertiary centre with pediatric pulmonology and rare disease capability; Indus Hospital and Health Network in Karachi with pediatric subspecialty capacity; Pakistan Kidney and Liver Institute (PKLI) in Lahore; Combined Military Hospitals (CMH) in Rawalpindi and Lahore; and Shifa International Hospital in Islamabad. For families whose treating CF specialist is at a smaller institution, the practical route is to coordinate with one of the above centres as the dispensing facility while the treating physician retains clinical oversight, or to use a DRAP-licensed specialty importer based in Karachi or Lahore.

5. Real cost picture for Alyftrek in Pakistan

The Pakistani Rupee has been volatile across the last several years. As of May 2026 the USD to PKR rate is in the 278 to 280 range, with annual CPI inflation rising to 10.9 percent in April 2026. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source. Families with overseas relatives often consolidate funds in USD before disbursing. 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 PKR 7.9 million per 28-day pack and PKR 103 million per annual course at the May 2026 exchange rate). 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 and copay 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 Karachi or Lahore typically runs USD 400 to USD 800 per shipment and does not require gel packs, dry ice, or active temperature loggers.

Third, regulatory and coordination. DRAP documentation handling fees, FBR Customs clearance, and Reserve Meds' concierge fee are itemised separately. On the insurance side, Adamjee Insurance, Jubilee General Insurance, EFU Health, State Life, IGI, and Pak-Qatar Family Takaful handle named-patient imports case by case, with chronic CFTR modulator therapy of this kind typically outside formulary. The realistic operating default is cash-pay with annual budgeting from the first case, and Pakistani CF families frequently fund Alyftrek through pooled household resources including remittances from relatives in the GCC, UK, and North America.

6. Typical timeline for Alyftrek in Pakistan

The DRAP timeline for routine Personal Use Import cases runs four to eight weeks from a complete submission; complex first-import CFTR modulator cases into a given Pakistani institution can extend to ten to sixteen weeks. Alyftrek is an ambient oral tablet, so cold-chain transit time does not apply. End-to-end, a typical Alyftrek case in Pakistan runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; three to seven days for the treating CF specialist and the dispensing hospital's import pharmacy to assemble the application with CFTR genotype documentation; four to eight weeks for DRAP review through the OIES portal (longer for first-time CFTR modulator imports into the institution); three to five days for US sourcing through Vertex's contracted specialty pharmacy channel under DSCSA-compliant chain-of-custody; one to three days for qualified ambient shipment; two to four days for FBR Customs clearance at Karachi seaport or Lahore or Islamabad airport under the DRAP NOC; 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.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the DRAP application. The treating Pakistani CF specialist documents the diagnosis of cystic fibrosis with ICD-10 coding and supporting evidence (sweat chloride, sinopulmonary phenotype, pancreatic insufficiency where applicable); 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 a 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); 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 PMDC license verification, the institutional pharmacy license, the requested pack count and refill plan, and the chain-of-custody plan for the ambient shipment. Post-import, the treating physician and dispensing pharmacy commit to adverse-event reporting through the DRAP Pharmacovigilance Centre for the full course of therapy.

8. Common questions about Alyftrek in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Alyftrek? Coverage for named-patient CFTR modulator imports is uncommon across Pakistani health plans, particularly given the chronic indefinite nature of therapy and the annual budget impact. Some plans pay a partial percentage on a case-by-case basis. We supply the documentation; the claim is yours or your hospital's to file. The realistic default is cash-pay with annual planning.

How does Sehat Sahulat interact with named-patient Alyftrek imports? The Sehat Sahulat Program's Rs. 1,000,000 per family per year ceiling does not stretch to cover the cost of Alyftrek at the US WAC price point of roughly USD 370,000 per year, and the program is structured around in-network empaneled hospital treatment rather than imported drug procurement. Patients can use Sehat Sahulat for hospitalisation and supportive CF care while Alyftrek is procured separately on cash-pay.

Will my PMDC-licensed pediatric pulmonologist's letter be sufficient if DRAP queries the case? Yes. PMDC-licensed pediatric pulmonologists and adult pulmonologists with CF expertise at AKUH, SKMCH&RC, the Children's Hospital and Institute of Child Health in Lahore, Indus, PKLI, CMH, and Shifa International all have signing authority on Personal Use Import applications.

Is CFTR genotype testing available in Pakistan? Yes, at a limited number of centres. AKUH genomics services and SKMCH&RC molecular pathology run CFTR mutation panels, and some patients obtain testing via international reference laboratories. Comprehensive next-generation sequencing panels that detect the full Alyftrek-covered mutation set are increasingly available. The testing laboratory is identified in the DRAP 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 include hypersensitivity reactions, drug interactions via CYP3A, and cataracts in pediatric patients (a class effect across CFTR modulators). The most common adverse reactions in SKYLINE 102 and SKYLINE 103 were generally consistent with the Trikafta safety profile. There is no REMS program; the boxed warning is managed by the LFT monitoring schedule.

Why this drug versus Trikafta? Alyftrek is once-daily; Trikafta is twice-daily. Alyftrek covers approximately 31 additional CFTR mutations on the label. In SKYLINE 102 and 103, 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.

9. Where Reserve Meds fits in Alyftrek cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating CF specialist, DRAP, 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 including the approximately 31 non-Trikafta mutations now covered, 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 Pakistani 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 ›

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