Trikafta access in Egypt: the EDA named-patient pathway

How families in Egypt obtain Trikafta (elexacaftor, tezacaftor, ivacaftor) for cystic fibrosis through the Egyptian Drug Authority personal importation framework.

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

Quick orientation

Trikafta is the Vertex Pharmaceuticals triple-combination CFTR modulator approved by the US FDA in October 2019 for cystic fibrosis patients aged 2 years and older who carry at least one F508del mutation in the CFTR gene. Cystic fibrosis is less common in the Egyptian population than in Northern European cohorts, but the diagnosis is now consistently made by the pediatric pulmonology services at Cairo's major academic hospitals, and the F508del allele is the most frequently identified pathogenic variant among Egyptian patients who do have CF. Trikafta is registered in many regulated markets and broadly available in Europe and the Gulf, but routine retail stocking in Egypt is limited and most cases run as named-patient imports. The Egyptian Drug Authority (EDA), established by Law No. 151 of 2019, is the authority that processes the personal importation permit through the patient's dispensing hospital.

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Why families in Egypt reach for Trikafta through NPP

Egypt is the most populous country in the MENA region and operates one of the most active named-patient import workflows in the Arab world. Three structural access gaps appear repeatedly in Egyptian patient cases: a medicine can be on the EDA register but absent from the hospital pharmacy that needs it; a medicine can be registered for one indication and prescribed for another FDA-approved use that is not on the local label; or a medicine can never have been registered locally because the Egyptian patient population is small. For Trikafta the dominant pattern is the third. CF prevalence in Egypt is meaningfully lower than in European reference populations, so the routine commercial case for a Vertex-led EDA registration push has not been compelling. Families whose child has been diagnosed at the pediatric pulmonology service at Cairo University Hospitals (Kasr Al Ainy), Ain Shams University Hospitals, or one of the large private centers therefore look for a cross-border channel to obtain a drug that is broadly used in Europe and the United States but not consistently stocked in Cairo.

The named-patient case for Trikafta also rests on the drug itself. Roughly 90 percent of people with cystic fibrosis carry at least one F508del allele, which is the eligibility gate for Trikafta. The pediatric label was extended to ages 6 and older in June 2021, then to ages 2 and older in April 2023, which broadened the population of Egyptian children eligible for the drug at the youngest age. Vertex launched the once-daily successor Alyftrek (vanzacaftor, tezacaftor, deutivacaftor) in the United States in December 2024, but Trikafta has longer real-world experience and broader international registration coverage, and families who have already established response on Trikafta typically prefer to continue rather than switch.

The EDA personal importation pathway for Trikafta

EDA was created by Law No. 151 of 2019, issued in the Official Gazette on 25 August 2019, with executive regulations issued by Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA is a public service authority affiliated with the Prime Minister and consolidates functions previously held by NODCAR, NORCB, and the Ministry of Health's Central Administration of Pharmaceutical Affairs. The EDA Drug Registration Sector handles registration files, and the Egyptian Pharmacovigilance Center (EPVC) handles post-market safety.

EDA permits the importation of unregistered medicines for a specific patient when no equivalent registered product is available locally, or when the available quantity of an equivalent registered product cannot meet the patient's clinical need. This is the pathway commonly described as Personal Importation, with Special Access and Compassionate Use appearing as variations in EDA correspondence. The application is filed through the dispensing institution's import pharmacy, typically a private specialty hospital, a university hospital import desk, or a licensed specialty importer in Cairo acting on the patient's behalf.

For Trikafta the clinical justification angle is genotype-specific. A complete application typically includes:

- A clinical justification letter on hospital letterhead from the treating CF pulmonologist, naming the patient's CFTR genotype (at least one F508del mutation, or another responsive variant on the current FDA label), prior modulator history if any, clinical status, and the specific clinical reason this drug is required rather than a locally available alternative
- A recent prescription specifying brand name (Trikafta), generic name (elexacaftor, tezacaftor, ivacaftor), strength, dosage form, and quantity required
- A patient identifier (national ID card or passport) plus Egyptian Medical Syndicate membership number and Ministry of Health licence reference for the treating physician
- Product details: manufacturer Vertex Pharmaceuticals, country of origin (United States), FDA approval reference, shelf life, storage conditions (room temperature, no refrigeration)
- The destination dispensing facility licence and a chain-of-custody plan from the US specialty pharmacy through to the dispensing hospital pharmacy

Routine EDA personal-import authorisations for well-documented pediatric rare-disease cases typically run in a 3 to 6 week window once a complete package is submitted, though this range varies meaningfully by case complexity and whether supplementary documentation is requested mid-review. EDA reserves discretion at every step. Trikafta is room-temperature stable, so timelines are not constrained by cold-chain logistics, but pediatric granule packets for patients ages 2 to 5 carry their own dispensing-pharmacy verification steps. Reserve Meds does not promise EDA timelines and is not the filer.

Where Trikafta gets dispensed in Egypt

Trikafta is an oral therapy taken twice daily, so there is no infusion-centre requirement and the dispensing footprint is broader than for cold-chain biologics. For pediatric CF cases the natural homes are the pediatric pulmonology services at the largest academic hospital networks, where genetic testing for the F508del allele and routine CF follow-up are already established. The Egyptian institutions with the import-pharmacy infrastructure and pediatric experience to handle Trikafta as routine workflow include Cairo University Hospitals (Kasr Al Ainy), the largest academic hospital network in Egypt and the Middle East, with a dedicated Drug Information

Center and pediatric services; Ain Shams University Hospitals, the second major academic network in Cairo, with strong pediatric pulmonology; and Children's Cancer Hospital Egypt 57357 for pediatric patients with overlapping oncology indications, which operates the first pharmacogenetics unit of its kind in Egypt.

On the private-sector side, Dar Al Fouad Hospital in 6th of October City (part of the Alameda Healthcare Group, JCI-accredited, signed a cooperation agreement with the Cleveland Clinic in 1999), As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group facilities handle named-patient imports as routine and have the pediatric specialty infrastructure for CF follow-up. Smaller hospitals outside Cairo, Giza, and Alexandria typically route Trikafta cases through one of these centres or through a licensed Cairo-based specialty importer that files the EDA permit and delivers under chain-of-custody to the prescribing hospital pharmacy. Cairo International Airport is the dominant import gateway, with secondary capacity at Alexandria.

Real cost picture for Trikafta in Egypt

Reserve Meds quotes Egyptian patients in US dollars and accepts USD wire transfers. The Egyptian pound (EGP) has lost more than 70 percent of its value against the dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026 and a controlled-depreciation outlook through end of year per IMF Article IV forecasts. Quoting in USD insulates the family from intra-case currency drift between quote and shipment, which matters meaningfully for a chronic therapy that is filled month after month.

US wholesale acquisition cost for Trikafta is approximately USD 322,000 per patient per year, which works out to roughly USD 26,800 per month for adult-strength dosing. The named-patient acquisition cost sits between US WAC and confidential negotiated payer prices in Europe and is finalised only on firm-quote issuance after document review. International logistics for Trikafta runs at the lower end of the Reserve Meds lane range because the product is ambient-controlled rather than cold-chain, typically USD 400 to USD 800 for the international leg into Cairo. EDA permit handling fees on the Egyptian side are nominal relative to the drug itself and are itemised by the dispensing facility. Many Egyptian families coordinate USD funds via relatives in the Gulf, the UK, or North America, where USD is readily available. On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and MedGulf Egypt each assess named-patient imports case by case. The Universal Health Insurance Authority (UHIA) does not currently cover most specialty imports for most patients.

Typical timeline for Trikafta in Egypt

For an established CF patient with a clean F508del genotype letter, a current weight-band confirmation, and a pediatric pulmonology referral from one of the major academic or private hospitals, the typical end-to-end cycle is 5 to 9 weeks. The EDA permit step generally runs 3 to 6 weeks for routine pediatric rare-disease cases. US-side sourcing and release through the Vertex specialty-pharmacy network adds approximately 1 to 2 weeks. International ambient-controlled transit and Egyptian customs clearance under the import permit are typically 4 to 7 days. For first-time imports through a smaller importer, for cases involving non-F508del responsive variants requiring extra label review, or for granule-packet pediatric dispensing requiring additional pharmacy verification, the front-end EDA step can extend to 8 to 14 weeks. Timelines are presented as typical ranges and not as promises; specific dates are confirmed at firm-quote issuance.

What your physician needs to provide

The clinical justification letter for Trikafta is the centrepiece of the EDA package. For this product the letter typically includes:

- The patient's confirmed cystic fibrosis diagnosis and CFTR genotype (at least one F508del allele documented on the genetic-testing report, or another responsive variant on the current FDA label)
- The patient's current age and weight, with the weight band that determines the appropriate Trikafta strength (adult strength for patients aged 12 and older or pediatric patients 25 kg and above; lower-strength tablet for patients 6 to 11 under 25 kg; granule packets for patients ages 2 to 5 in two weight bands at 10 kg and 14 kg thresholds)
- Prior CF treatment history and any prior CFTR-modulator exposure (Kalydeco, Orkambi, Symdeko, or Trikafta itself)
- Justification for why a locally registered alternative is not suitable, which for Trikafta in Egypt is typically the absence of a clinically equivalent on-label triple-combination modulator on the EDA register
- The dosing plan: morning tablet plus evening tablet 12 hours apart, both with fat-containing food, since ivacaftor absorption increases roughly three-fold with dietary fat
- The monitoring plan: baseline and periodic liver function tests (ALT, AST, bilirubin) every three months for the first year then annually; baseline and follow-up ophthalmologic examination in pediatric patients for cataracts; medication reconciliation for CYP3A interactions, with rifampin and St John's wort contraindicated and strong inhibitors requiring dose reduction to twice-weekly

The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference anchor the application. Both public-sector physicians at Kasr Al Ainy, Ain Shams, and 57357 and private-sector physicians at Dar Al Fouad, As-Salam, Cleopatra, and the other major private hospitals have signing authority on personal-import clinical justification letters, subject to the institutional licence of the dispensing hospital.

Common questions about Trikafta in Egypt

Will Bupa Egypt, AXA, MetLife, or Allianz cover Trikafta? Each insurer assesses named-patient imports case by case. Some plans reimburse a percentage when the drug treats a covered indication even if the specific product is not on a local formulary, and many require pre-authorisation. We do not promise coverage. We supply the documentation an insurer would request; the claim itself remains with you or the dispensing hospital.

Does UHIA cover Trikafta? Not as a general rule. The UHI rollout began in Port Said in 2019 and is phased through to 2032, with Cairo, Giza, and Qalyubia in the final phase. For most named-patient specialty imports in 2026, UHIA is not the funding path; cash-pay in USD or private insurance reimbursement is the realistic posture.

How do we handle USD payment given EGP volatility? Reserve Meds quotes in USD and accepts USD wire transfers. Many Egyptian families coordinate USD funds via relatives in the UAE, Saudi Arabia, Kuwait, Qatar, the UK, or the US. The transparent USD quote means you know exactly what to wire regardless of intra-case EGP movement.

What if my child is under 2 years old? Trikafta is approved for patients aged 2 years and older. Reserve Meds will not coordinate intake for a patient outside the FDA-approved age range.

What about Alyftrek? Alyftrek is Vertex's once-daily successor approved by the FDA in December 2024. Trikafta has longer real-world experience, broader international registration, established payer pathways, and in several markets a lower acquisition cost. Switching is a clinician-driven decision and not one Reserve Meds makes.

Can we receive the medicine at home? The dispensing facility must hold a valid Egyptian pharmacy or hospital licence. For Trikafta, the medicine moves into a hospital outpatient pharmacy or a specialty importer pharmacy, and the family collects it from there. Direct-to-home delivery without a licensed dispensing facility in the chain is not the model.

Where Reserve Meds fits in Trikafta cases

Reserve Meds is a US-based concierge coordinator. We do not replace your CF physician, do not replace EDA, and do not replace the dispensing pharmacy. For Trikafta specifically we orchestrate the US-side sourcing through the Vertex specialty-pharmacy network, prepare the regulatory documentation kit your physician needs for the EDA filing (genotype letter template, dosing reference by weight band, monitoring plan summary), coordinate the international ambient-controlled logistics to Cairo International Airport, and run a single named coordinator throughout the case in both English and Arabic. F508del genotype documentation, CF center referral letter, and current weight-band confirmation are mandatory intake artefacts. We do not coordinate off-label use, and we will decline intake for patients without at least one F508del allele or another labeled CFTR-responsive variant.

Next step

If your CF physician has decided Trikafta is the right next step and local stocking is the bottleneck, the named-patient pathway through EDA is the route. Join the waitlist below and we will confirm eligibility within 24 to 48 hours and route the documentation kit to your physician.

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