

## Trikafta

Oman · access guide

# How to access Trikafta from Oman, the named-patient import pathway, 2026

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

A Omani patient with cystic fibrosis in patients aged 2 years and older with at least one F508del mutation in the CFTR gene or another mutation responsive to elexacaftor/tezacaftor/ivacaftor in vitro may receive a prescription for Trikafta (elexacaftor, tezacaftor, and ivacaftor) from their treating cystic fibrosis specialist. Trikafta is FDA-approved in the United States and manufactured by Vertex Pharmaceuticals. It is a triple-combination CFTR modulator administered by oral tablet. Local availability of Trikafta in Oman can be inconsistent: the drug may not be on every specialty pharmacy's standing formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through DGPADC remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

## The clinical situation

Trikafta is a triple-combination CFTR modulator. Mechanism: elexacaftor and tezacaftor are CFTR correctors that improve folding and trafficking, and ivacaftor is a CFTR potentiator that enhances chloride transport. Dosing: two morning tablets of elexacaftor 100 mg / tezacaftor 50 mg / ivacaftor 75 mg and one evening tablet of ivacaftor 150 mg in adults, with fat-containing food, per FDA labeling. Baseline workup per FDA labeling includes CFTR mutation confirmation, baseline FEV1, sweat chloride, liver function tests, and ophthalmologic baseline in paediatric patients. Other important warnings include elevated liver function tests and drug-induced liver injury (including patients with prior liver disease), drug interactions with strong CYP3A inducers and inhibitors, and lens opacities in paediatric patients. Your specialist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

## Is Trikafta legally importable into Oman?

Yes, through Oman Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. Oman has an established pathway for specialty medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The DGPADC named-patient route allows a Omani-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility. Applications are typically filed through the dispensing institution's import pharmacy on the physician's behalf, with approval issued on a per-patient, per-cycle quantity basis.

## How the pathway works, step by step

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1. **Consultation with your treating specialist.** The prescribing decision is clinical. Your specialist documents the indication, prior therapies where relevant, and rationale for Trikafta.
2. **Baseline screening.** CFTR mutation confirmation, baseline FEV1, sweat chloride, liver function tests, and ophthalmologic baseline in paediatric patients are confirmed and documented.
3. **DGPADC named-patient application.** Your specialist or the facility's import pharmacy files the application with clinical rationale, patient reference, product strength, quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from Vertex Pharmaceuticals's authorised distribution under DSCSA chain-of-custody.
5. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your specialist initiates therapy.

## What documentation your physician needs

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Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, prior therapies where relevant, and Trikafta as the indicated next step
- Verification of their Omani medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above)
- The planned dosing regimen (two morning tablets of elexacaftor 100 mg / tezacaftor 50 mg / ivacaftor 75 mg and one evening tablet of ivacaftor 150 mg in adults, with fat-containing food, per FDA labeling)
- A monitoring plan covering CFTR mutation report, baseline FEV1 and LFTs, and CYP3A interaction screen

Reserve Meds provides a physician documentation kit tailored for CFTR modulator therapies, including the templates DGPADC reviewers commonly request.

## Typical costs and indicative timing

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Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for a typical month of daily dosing of Trikafta sits in an indicative 2026 band of approximately USD 26,000 to 32,000. International logistics, DGPADC documentation handling, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 2 to 5 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the dosing schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

## Where Reserve Meds fits in

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Trikafta specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for DGPADC review, including CFTR modulator class templates.
- **Logistics.** Internationally tracked shipment to your named dispensing facility with tamper-evident packaging.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating specialist, and dispensing sits with the licensed Omani pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

## Frequently asked

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**Is this legal in Oman?** Yes, when executed through the DGPADC named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at Omani tertiary centers.

**Will my private health insurance cover this?** Cash-pay is the default posture. Some Omani private insurers reimburse named-patient imports on a case-by-case basis. We supply documentation for your submission but do not process insurance claims.

**What if my physician has not filed a named-patient request before?** Named-patient import is an institutional process most major Omani tertiary centers (Sultan Qaboos University Hospital (SQUH), Royal Hospital Muscat, and Oman Oncology Center) have encountered. Our documentation kit is written for first-time applicants and tracks what DGPADC reviewers commonly ask for.

## ***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.

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### **Reserve Meds**

*reserved for you.*

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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