Praluent access in the UAE: the EDE named-patient pathway

How patients in the United Arab Emirates obtain US-sourced Praluent (alirocumab) for familial hypercholesterolemia and cardiovascular risk reduction when local stocking lags the prescription.

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

Quick orientation

Praluent (alirocumab) is a fully human IgG1 monoclonal antibody that targets PCSK9 to lower LDL cholesterol. It is FDA-approved for heterozygous familial hypercholesterolemia, established atherosclerotic cardiovascular disease, homozygous familial hypercholesterolemia, and reduction of major cardiovascular events. Across the United Arab Emirates, Praluent is locally registered through MOHAP, yet specialty stocking varies materially by emirate, by pharmacy, and by month. For a patient titrated to a specific Praluent dose or specifically requesting alirocumab rather than evolocumab, the gap between a written prescription and a filled pen is real, and it is the gap a named-patient pathway closes. Reserved for you.

Why patients in the UAE need Praluent via NPP

The UAE operates one of the most developed pharmaceutical regulatory environments in the GCC. The federal Ministry of Health and Prevention (MOHAP) maintains the national drug register, and the Emirates Drug Establishment (EDE), which assumed 44 core services from MOHAP on 29 December 2025 under Federal Decree-Law No. 38 of 2024, now administers marketing authorisations, import permits, and pharmacovigilance oversight. Praluent has been registered with MOHAP through Sanofi's local agent network, so the drug is on the UAE register.

Registration, however, does not guarantee shelf presence. Praluent in the UAE typically falls into the first of three structural access gaps documented in the UAE country module: registered but not stocked. Pharmacy-level stocking is tender-driven, and the 75 mg, 150 mg, and 300 mg presentations are not consistently held across all hospital pharmacies. A patient may also specifically prefer Praluent over Repatha (evolocumab), the other PCSK9 inhibitor, on the basis of prior tolerability, the 300 mg every-4-weeks dosing option, or specialist recommendation. Where the locally stocked PCSK9 inhibitor is Repatha and the patient or prescriber wants Praluent, the named-patient route makes that preference executable. None of this involves off-label use. Praluent is being routed to a UAE patient for an FDA-approved indication, through the standard UAE unregistered-or-not-stocked import permit corridor, rather than through a domestic retail script.

The EDE named-patient pathway for Praluent

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit. From 29 December 2025, this is administered through the EDE portal at ede.gov.ae. The framework permits hospitals and

licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority. Praluent qualifies cleanly: it holds FDA approval (since July 2015), EMA marketing authorisation (since September 2015), MHRA, Health Canada, and PMDA Japan approvals.

For Praluent specifically, the clinical justification angle in the EDE application typically anchors on one of three patterns. For a heterozygous familial hypercholesterolemia patient, the letter documents LDL-C at baseline and after maximally tolerated statin and ezetimibe, why a PCSK9 inhibitor is the appropriate next-line agent, and why Praluent rather than Repatha is the prescriber's choice. For a homozygous FH patient, the letter references the 150 mg every-2-weeks regimen specific to HoFH and the requirement for adjunctive LDL-lowering therapies. For an ASCVD patient post-myocardial infarction or post-acute coronary syndrome, the letter cites the ODYSSEY OUTCOMES cardiovascular risk reduction evidence and the patient's residual cardiovascular risk after high-intensity statin therapy.

A complete application includes the clinical justification letter from the treating physician, UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location), patient identifier (anonymised where the EDE submission allows), full product details (brand name, generic name alirocumab, manufacturer Regeneron or Sanofi depending on origin lot, strength 75 mg or 150 mg or 300 mg, pre-filled pen presentation, pack size, treatment duration), the destination dispensing facility name and license number, and a chain-of-custody plan describing how the refrigerated biologic moves from US specialty distribution to the UAE importer to the dispensing pharmacy with continuous temperature monitoring.

Approval timelines for routine Praluent cases are typically 5 to 15 business days. Complex cases, such as larger quantity requests intended to cover a full year of every-2-week dosing in one shipment, can extend to 4 to 6 weeks. The EDE may seek clarification on whether the locally registered PCSK9 inhibitor has been considered and why it is not suitable, which the clinical letter addresses upfront.

Where Praluent gets dispensed in the UAE

Praluent is a refrigerated biologic that does not require infusion-suite administration. The patient self-administers subcutaneously after training. The dispensing facility list narrows from the full UAE specialty hospital network to those institutions with validated 2 to 8 degree Celsius pharmacy storage and a training capacity for self-injection biologics. In practice this includes Cleveland Clinic Abu Dhabi (M42 group, Al Maryah Island), Sheikh Khalifa Medical City (SEHA network, managed by Cleveland Clinic), American Hospital Dubai (Mayo Clinic Care Network member), King's College Hospital London Dubai (with strength in cardiology and endocrinology), Mediclinic City Hospital in Dubai Healthcare City, and the larger NMC Healthcare cardiology service lines.

For a Northern Emirates resident or a patient outside the major centers, the standard route is through a Dubai- or Abu Dhabi-based specialty importer that holds a pharmaceutical establishment license, files the EDE permit on the prescribing physician's behalf, clears the medicine through customs, and delivers under chain-of-custody documentation to the prescribing hospital's outpatient pharmacy. The patient then collects the pen and receives injection training at that pharmacy or through a clinic visit.

Real cost picture for Praluent in the UAE

Following the February 2019 list price reduction by Sanofi and Regeneron, the US wholesale acquisition cost (WAC) for Praluent is approximately USD 5,850 per year for both the 75 mg and 150 mg strengths, equating to roughly USD 450 to 500 per pen at typical Q2W dosing. The AED is pegged to the US dollar at approximately 3.67 AED to 1 USD, so a year of Praluent at US list translates to approximately AED 21,500 before any logistics, customs, or coordination overhead.

The all-in delivered-to-UAE cost typically includes the US drug acquisition, cold-chain international logistics in the USD 400 to 1,500 (approximately AED 1,500 to 5,500) range depending on shipment size and destination emirate, nominal EDE permit and UAE customs fees, regulatory documentation handling, and the Reserve Meds coordination fee. Three- and six-month supply windows reduce the per-month logistics overhead. Reserve Meds quotes an indicative range at intake and a firm itemised quote after documentation review.

On the insurance side, UAE health insurance is mandatory and operates through Daman National Health Insurance (operator of Thiqa for UAE nationals), GIG Gulf, Sukoon Insurance, ADNIC, Orient Insurance, and others. Each insurer assesses PCSK9 inhibitor named-patient imports case by case. Some plans reimburse fully when the medicine is on formulary even if not stocked, some reimburse a percentage, and many require pre-authorisation. Cash-pay is the default posture; many UAE patients reimburse themselves after the fact if their plan covers.

Typical timeline for Praluent in the UAE

From waitlist submission to first pen in hand, the typical Praluent case runs as follows. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to the treating physician. The physician or hospital import pharmacy or specialty importer files the EDE permit application, which clears in 5 to 15 business days for routine cases. In parallel, Reserve Meds aligns US-side specialty pharmacy sourcing and the cold-chain shipment plan. Once the permit is issued, US release and shipment add 5 to 10 business days for a validated 2 to 8 degree Celsius cold-chain transit, including customs clearance into the importer's bonded warehouse or directly to the hospital. The full cycle for an initial 90-day supply is typically 3 to 5 weeks. Re-supply on a chronic-therapy cadence aligns with the patient's titration check-ins.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDE Praluent package. The letter, on the prescribing institution's letterhead and signed by a UAE-licensed physician practicing in the emirate of the dispensing facility, typically includes: diagnosis (heterozygous FH, homozygous FH, established ASCVD, or a combination), severity markers including LDL-C at baseline and on current therapy, the full prior-therapy history (statin class and dose, statin intolerance documentation where applicable, ezetimibe trial, bempedoic acid trial where relevant), the rationale for PCSK9 inhibitor therapy now, the rationale for Praluent specifically rather than Repatha, the proposed dosing plan (75 mg or 300 mg starting dose, plan for titration to 150 mg Q2W if LDL-C response is inadequate at 8 weeks, or the HoFH-specific 150 mg Q2W regimen), the monitoring plan including LDL-C at 4 to 8 weeks post-initiation, and patient training plan for subcutaneous self-administration.

The physician also confirms their UAE medical license is in active standing at the time of filing. License-status transitions, such as a non-Emirati physician's credential renewal or transfer between employers, can pause an application, so confirming active status at the moment of

submission is good practice. For a pediatric heterozygous FH patient, the letter references the pediatric label additions and weight-adjusted considerations where applicable, and the dispensing facility's pediatric service capability.

Common questions about Praluent in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Praluent?

Each insurer assesses PCSK9 inhibitor named-patient imports case by case. Some reimburse in full when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and several require pre-authorisation. Thiqa, the government-funded programme for UAE nationals administered by Daman, has the broadest specialty coverage in Abu Dhabi. We do not promise coverage from any insurer. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Will my DHA-licensed, DOH-licensed, or MOHAP-licensed physician's letter be sufficient?

Yes. Any UAE-licensed physician practicing in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter. A DHA-licensed cardiologist or lipid specialist in Dubai, a DOH-licensed cardiologist in Abu Dhabi, or a MOHAP-licensed specialist in the Northern Emirates can each anchor a Praluent application in their jurisdiction.

Can I receive Praluent at home, or do I need a hospital?

The dispensing facility must be UAE-licensed. Praluent is patient-administered subcutaneously, so once dispensed through a UAE-licensed hospital outpatient pharmacy or import pharmacy and after injection training, the patient self-administers at home. Direct-to-home delivery without a licensed dispensing facility in the chain is not the model.

What is the safety profile for Praluent?

The most common adverse reactions in the FDA-approved labeling are injection-site reactions, nasopharyngitis, and influenza-like symptoms. Hypersensitivity reactions have been reported, including rare cases requiring discontinuation. The product carries no boxed warning. The full safety profile is documented in the FDA package insert and the EMA SmPC, and the prescribing physician monitors per current guidelines.

How is the response to Praluent monitored?

LDL-C is typically measured 4 to 8 weeks after initiation or dose change to assess response and inform any dose adjustment. There is no routine hepatic or hematologic monitoring requirement attached to the label. Injection-site reactions and signs of hypersensitivity are assessed at each visit.

Why Praluent rather than Repatha?

Both products achieve substantial LDL-C reduction and both carry cardiovascular outcomes evidence (ODYSSEY OUTCOMES for Praluent, FOURIER for Repatha). Selection is driven by prescriber familiarity, local stocking, patient tolerability, dosing-frequency preference (Praluent offers a 300 mg every-4-weeks option), and prior treatment response. Reserve Meds does not promote one over the other; the named-patient pathway supports either based on the prescription written.

Where Reserve Meds fits in Praluent cases

Reserve Meds is a US-based concierge coordinator. We do not replace the treating cardiologist or lipidologist, do not replace the EDE or any emirate-level authority, and do not replace the UAE dispensing pharmacy. What we do is orchestrate US-side specialty pharmacy sourcing, the regulatory documentation kit the treating physician needs, the cold-chain international logistics under chain-of-custody, and a single named coordinator through the case. Praluent integrates with the same 2 to 8 degree Celsius fulfillment partners used for other refrigerated biologics in the Reserve Meds matrix. No prior Reserve Meds case experience with Praluent specifically at the time of this page; standard NPP coordination applies, and the chronic-therapy cadence aligns naturally with quarterly re-supply windows.

Next step

If the cardiologist or lipidologist has recommended Praluent and the UAE pharmacy supply is not aligned with the patient's prescription, the waitlist is the first step. We confirm eligibility within 24 to 48 hours and send the physician documentation kit.

Reserved for you.

This guide is informational, not medical or legal advice. The EDE named-patient framework requires a licensed UAE physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.