Praluent access in Egypt: the EDA named-patient pathway

How patients in Egypt obtain US-sourced Praluent (alirocumab) for familial hypercholesterolemia and cardiovascular risk reduction when local PCSK9 inhibitor stocking does not align with the prescription.

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Quick orientation

Praluent (alirocumab) is a fully human IgG1 monoclonal antibody that inhibits PCSK9 to lower LDL cholesterol. It is FDA-approved for heterozygous familial hypercholesterolemia (HeFH), established atherosclerotic cardiovascular disease (ASCVD), homozygous familial hypercholesterolemia (HoFH), and reduction of myocardial infarction, stroke, and unstable angina hospitalization in adults with established cardiovascular disease. Across Egypt, the PCSK9 inhibitor class has import-track activity through the Egyptian Drug Authority (EDA), but pharmacy-level stocking is tender-driven and inconsistent. For a patient with familial hypercholesterolemia identified through cascade screening at the Magdi Yacoub Heart Foundation, or a post-acute coronary syndrome patient whose cardiologist has selected Praluent specifically, the named-patient pathway closes the gap between a written prescription and a filled pen. Reserved for you.

Why patients in Egypt need Praluent via NPP

Egypt is the most populous country in the MENA region and runs one of the most active named-patient import workflows in the Arab world. Cardiovascular disease is the leading cause of mortality in Egypt, and the country carries a notable familial hypercholesterolemia burden that is being characterised through formal cascade screening programmes such as the work led by the Magdi Yacoub Heart Foundation. Despite this clinical demand, the PCSK9 inhibitor class in Egypt sits in the country module's first structural access gap: import-track activity exists but broad commercial penetration does not. Pharmacy-level stocking depends on tender cycles and specialist prescribing volume, particularly outside major Cairo, Giza, and Alexandria tertiary-care hubs.

Three patterns drive Praluent demand in Egypt specifically. First, stocking variability, where a patient referred to start PCSK9 therapy finds the hospital pharmacy has no inventory and a multi-week reorder lead time. Second, patient or prescriber preference between PCSK9 options. Where Repatha (evolocumab) is the locally encountered PCSK9 inhibitor through Amgen's regional agents, a patient or cardiologist may prefer Praluent on the basis of prior tolerability, the 300 mg every-4-weeks dosing option, or specialist recommendation. Third, pediatric familial hypercholesterolemia. Cascade screening identifies pediatric heterozygous FH patients whose lipid trajectory warrants PCSK9 therapy, and the pediatric label additions for alirocumab give those families a documented route. None of these scenarios involves off-label use. The patient is using Praluent for an FDA- and EMA-approved indication, simply routed through the EDA personal-importation corridor rather than through a domestic retail script.

The EDA named-patient pathway for Praluent

The Egyptian Drug Authority (EDA) was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations issued by Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA permits the importation of unregistered or insufficiently available medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally or where the available quantity of an equivalent product cannot meet the patient's clinical need. This is the pathway commonly referred to as Personal Importation, with the application filed through the dispensing institution's import pharmacy: a private specialty hospital, a university hospital import desk, or a licensed specialty importer acting on the patient's behalf.

For Praluent specifically, the clinical justification angle in the EDA application anchors on one of four patterns. For a heterozygous familial hypercholesterolemia patient identified through cascade screening, the letter documents the FH diagnosis (clinical Dutch Lipid Clinic Network criteria, Simon Broome criteria, or genetic confirmation where available), LDL-C at baseline and after maximally tolerated statin and ezetimibe, and why a PCSK9 inhibitor is the appropriate next-line agent. 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 a post-acute coronary syndrome ASCVD patient, the letter cites the ODYSSEY OUTCOMES trial evidence (Schwartz et al., NEJM 2018) for cardiovascular risk reduction and the residual risk after high-intensity statin therapy. For a pediatric heterozygous FH case, the letter references the pediatric label additions, weight-adjusted considerations, and the pediatric service capability of the dispensing facility.

The standard application package includes the clinical justification letter on hospital letterhead with the physician's stamp, a recent prescription specifying brand name (Praluent), generic name (alirocumab), strength (75 mg, 150 mg, or 300 mg), dosage form (pre-filled pen, subcutaneous injection), and quantity required. The package also requires a copy of the patient national ID or passport, the treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference, full product details including manufacturer (Regeneron or Sanofi depending on origin lot), country of origin, the FDA approval reference (BLA 125559, July 2015), shelf life and storage conditions, the destination dispensing facility licence, and a chain-of-custody plan for the 2 to 8 degree Celsius cold-chain handling through customs at Cairo International Airport. Routine EDA personal-import authorisations for well-documented cases are typically processed in a 3 to 6 week window once a complete package is submitted, though this range varies by case complexity and biologic cold-chain considerations. EDA reserves discretion at every step; Reserve Meds does not promise EDA timelines and is not the filer.

Where Praluent gets dispensed in Egypt

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 Egyptian 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 Cairo University Hospitals (Kasr Al Ainy) with its Drug Information Center and lipidology service lines, Ain Shams University Hospitals with its cardiology and endocrinology programs, the Magdi Yacoub Heart Foundation as the leading cardiovascular centre for familial hypercholesterolemia cascade screening and adult and pediatric lipid management, As-Salam International Hospital with one of the most advanced cardiac centres in Egypt, Dar Al Fouad Hospital (Alameda

Healthcare Group, JCI-accredited since 2005, Cleveland Clinic cooperation since 1999), and the Cleopatra Hospitals Group's cardiology service lines across multiple Cairo facilities.

For a resident outside Cairo, Giza, or Alexandria, the standard route is for the case to be co-managed with one of these centres or routed through a Cairo-based licensed specialty importer that handles the EDA filing, customs clearance at Cairo International Airport, and final delivery to a licensed dispensing facility. The patient then collects the pen and receives injection training at that pharmacy or through a clinic visit. Self-administration thereafter happens at home with site rotation between thigh, abdomen, and upper arm per the FDA label.

Real cost picture for Praluent in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. 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 every-2-week dosing. The EGP has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026; quoting in USD insulates the patient from intra-case currency drift between quote and shipment.

The all-in delivered-to-Egypt cost typically includes the US drug acquisition at WAC plus margin, cold-chain international logistics from a US specialty distributor to Cairo International Airport in the USD 400 to 1,500 range depending on volume and route, regulatory documentation handling fees on the Egyptian side which vary by dispensing facility and importer, and the Reserve Meds coordination fee itemised on the firm quote. Three- and six-month supply windows reduce per-month logistics overhead and align with quarterly LDL-C check-ins.

On the insurance side, named-patient reimbursement varies meaningfully by carrier. Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, MedGulf Egypt, Orient Takaful, and Royal Insurance each assess PCSK9 inhibitor 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; many require pre-authorisation. The Universal Health Insurance Authority (UHIA) coverage is still rolling out by governorate phase under Law No. 2 of 2018 and does not currently cover most specialty imports for most patients. Cash-pay remains the dominant posture, and many Egyptian families reimburse themselves later if their private insurance covers a portion.

Typical timeline for Praluent in Egypt

From waitlist submission to first pen in hand, the typical Praluent case in Egypt runs as follows. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to the treating physician, with Arabic-language patient-facing summaries where the family requests them. The physician or hospital import pharmacy or specialty importer prepares and files the EDA personal-import application, which clears in 3 to 6 weeks for well-documented cases. In parallel, Reserve Meds aligns US-side specialty pharmacy sourcing and the cold-chain shipment plan. Once EDA authorisation is issued, US release and shipment add 5 to 10 business days for a validated 2 to 8 degree Celsius cold-chain transit to Cairo International Airport, with the dispensing facility or licensed importer handling customs clearance. The full cycle for an initial 90-day supply is typically 5 to 9 weeks. Re-supply on a chronic-therapy cadence aligns with the patient's quarterly LDL-C check-ins.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA Praluent package. The letter, on the prescribing institution's letterhead and signed and stamped by an EMS-registered Egyptian physician with an active Ministry of Health licence, typically includes: diagnosis (heterozygous FH, homozygous FH, established ASCVD, pediatric FH, 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 Q4W starting dose with planned up-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 the patient training plan for subcutaneous self-administration.

For pediatric heterozygous FH cases identified through Magdi Yacoub Heart Foundation cascade screening or other Egyptian FH programmes, the letter references the pediatric label additions, weight-adjusted considerations, and pediatric-specific monitoring. The physician also confirms their EMS membership and MoH licence are in active standing at the time of filing. Egyptian Health Council (EHC) examination status and continuing professional development standing are not blockers for personal-import filings, but active licence status at the moment of submission is.

Common questions about Praluent in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, Allianz, or Misr Insurance cover Praluent?

Each insurer assesses PCSK9 inhibitor 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; many require pre-authorisation. We do not promise coverage from any insurer. We supply the documentation set that allows your insurer to assess; the claim itself sits with you or your hospital.

Does UHIA cover specialty imports like Praluent?

Not as a general rule, and not consistently across governorates yet. 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 PCSK9 inhibitor imports in 2026, UHIA coverage is not the funding path; cash-pay or private insurance reimbursement is.

Can a pediatric familial hypercholesterolemia patient receive Praluent through this route?

Yes, the framework applies. Cascade screening programmes such as those led by the Magdi Yacoub Heart Foundation identify pediatric heterozygous FH patients whose lipid trajectory warrants PCSK9 therapy. The pediatric services at the Magdi Yacoub Heart Foundation, Kasr Al Ainy, Ain Shams, Dar Al Fouad, and As-Salam handle pediatric specialty imports routinely. Clinical justification letters for pediatric cases typically include weight-adjusted dosing and pediatric-specific monitoring requirements.

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 and the Egyptian Pharmacovigilance Center (EPVC) framework.

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, and the treating physician reports adverse events to EPVC per Egyptian pharmacovigilance obligations.

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 EDA, do not replace the Egyptian dispensing pharmacy, and do not act as an importer of record in Egypt. What we do is orchestrate US-side specialty pharmacy sourcing, prepare the regulatory documentation kit the treating physician needs for the EDA filing, coordinate the international cold-chain logistics to Cairo International Airport, and run a single named coordinator throughout your case in both English and Arabic. The local EDA filing, customs clearance, and final dispensing all remain with the licensed Egyptian dispensing facility. 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 LDL-C re-supply windows.

Next step

If the cardiologist, lipidologist, or pediatric lipid specialist has recommended Praluent and the Egyptian 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, with Arabic-language patient summaries where the family requests them.

Reserved for you.

This guide is informational, not medical or legal advice. The EDA personal-importation framework requires a licensed Egyptian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.