Praluent access in Saudi Arabia: the SFDA named-patient pathway

How patients in the Kingdom of Saudi Arabia obtain US-sourced Praluent (alirocumab) for familial hypercholesterolemia and cardiovascular risk reduction when local PCSK9 stocking lags the prescription.

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Quick orientation

Praluent (alirocumab) is a fully human IgG1 monoclonal antibody that binds PCSK9, increasing LDL receptor density on hepatocytes and lowering circulating LDL cholesterol. It is FDA-approved for heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia, established atherosclerotic cardiovascular disease, and reduction of major cardiovascular events. In the Kingdom of Saudi Arabia, Praluent is registered with the Saudi Food and Drug Authority through a Sanofi local agent. Hospital-level stocking is uneven across Riyadh, Jeddah, and the Eastern Province, and the Repatha-versus-Praluent choice often comes down to which pen the cardiology pharmacy can put in a patient's hand the same week the prescription is written. The SFDA Personal Importation Program closes that gap. Reserved for you.

Why patients in Saudi Arabia need Praluent via NPP

Saudi Arabia operates one of the most mature pharmaceutical regulatory frameworks in the Gulf Cooperation Council, and SFDA has run a well-developed named-patient framework for more than a decade. Praluent has been registered with SFDA through its local agent network, so the product is on the Kingdom register. As the country module notes, registration in Saudi Arabia does not guarantee that any given hospital pharmacy has the medicine on the shelf on the day the patient needs it. Stocking decisions sit with the institution rather than with SFDA, and tender cycles introduce real intermittence.

For Praluent specifically, three patterns drive named-patient demand inside Saudi Arabia. First, stocking variability. A cardiology patient referred to start PCSK9 therapy at a Saudi German Hospital outpatient clinic, an HMG facility in Riyadh, or a Dr. Soliman Fakeeh Hospital service line in Jeddah may find the pharmacy carries one of the three Praluent presentations (75 mg, 150 mg, or the 300 mg every-4-weeks pen) but not the specific strength the cardiologist titrated to. Second, patient preference between PCSK9 options. Where Repatha (evolocumab) is the locally stocked PCSK9 inhibitor, a patient or prescriber may prefer alirocumab on the basis of prior tolerability, the 300 mg Q4W dosing schedule, or the ODYSSEY OUTCOMES cardiovascular evidence base. Third, continuity of therapy. Patients who initiated Praluent during care in the US, the UK, or the EU and have since returned to Saudi Arabia typically want to remain on alirocumab rather than switch class members, and the PIP corridor preserves that continuity without an off-label maneuver.

The SFDA Personal Importation Program for Praluent

The SFDA Personal Importation Program is the lawful framework for a Saudi-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally available alternative is not suitable. Praluent qualifies cleanly: FDA-approved since July 2015, EMA-authorised since September 2015, MHRA and Health Canada and PMDA Japan registered. Applications are filed through the dispensing institution's import pharmacy or an SFDA-licensed specialty importer in Riyadh or Jeddah, and reviewed by SFDA's Drug Sector. Routine cases run 10 to 21 business days; complex cases extend to 6 to 10 weeks.

The clinical-justification angle in a Praluent PIP file depends on the indication. For a heterozygous familial hypercholesterolemia patient, the letter documents LDL-C at baseline and after maximally tolerated statin and ezetimibe, the rationale for PCSK9 inhibitor therapy now, and why alirocumab rather than evolocumab 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 including LDL apheresis where applicable. For an ASCVD patient post-myocardial infarction or acute coronary syndrome, the letter anchors on ODYSSEY OUTCOMES cardiovascular risk reduction evidence and the patient's residual risk after high-intensity statin therapy. For a pediatric FH case at KFSH&RC or KAMC, the letter references the pediatric FH literature, weight-appropriate dosing considerations, and the institution's pediatric lipid clinic capability.

The full application package includes the clinical justification letter on institutional letterhead, the treating physician's active Saudi Commission for Health Specialties (SCFHS) license verification in the relevant specialty (cardiology, endocrinology, or internal medicine with a lipid focus), an anonymised patient identifier in the format SFDA accepts, full product details (brand Praluent, generic alirocumab, manufacturer Regeneron, strength 75 mg or 150 mg or 300 mg, pre-filled pen presentation, lot, expiry, requested quantity, treatment duration), the destination dispensing facility SFDA license, and a chain-of-custody plan from US release through international transit to the receiving Saudi pharmacy. Because Praluent is a 2 to 8 degree Celsius cold-chain biologic, the plan must document continuous temperature monitoring, validated passive or active containers, and excursion-management protocols. The SFDA portal at sfda.gov.sa and the Ghad digital regulatory platform are the operational entry points.

Where Praluent gets dispensed in Saudi Arabia

Praluent is a refrigerated biologic that does not require infusion-suite administration. The patient self-administers subcutaneously after injection-technique training. The dispensing facility list narrows from the full Saudi specialty hospital network to those institutions with validated 2 to 8 degree Celsius pharmacy storage and a workflow for self-injection biologic training. In practice that includes King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah, with strong cardiology and lipid clinic infrastructure; King Abdulaziz Medical City and the Ministry of National Guard Health Affairs network in Riyadh and Jeddah; King Saud University Medical City; and the major private networks, Dr. Sulaiman Al Habib Medical Group, Saudi German Hospital, Dr. Soliman Fakeeh Hospital, and Dallah Hospital, which run cardiology and endocrinology outpatient clinics with established import-pharmacy workflow.

For a patient in the Eastern Province, Tabuk, Asir, or another region without an in-house import pharmacy at the treating institution, the standard route is to partner with an SFDA-licensed

specialty importer based in Riyadh or Jeddah. The importer files the PIP application, handles chain-of-custody documentation and customs clearance, and transfers the medicine under institutional license to the dispensing facility. The patient collects the pen at that pharmacy and receives injection training there.

Real cost picture for Praluent in Saudi Arabia

Following the February 2019 list price reduction by Sanofi and Regeneron, the US wholesale acquisition cost 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 Saudi riyal is pegged at approximately 3.75 SAR to 1 USD, so a year of Praluent at US list translates to approximately SAR 22,000 before any logistics, customs, or coordination overhead. The 300 mg every-4-weeks regimen distributes the same annual cost across fewer shipments.

The all-in delivered-to-Saudi cost typically includes US drug acquisition at WAC, cold-chain international logistics in the SAR 1,500 to 5,600 (USD 400 to 1,500) range depending on shipment size and destination city, SFDA regulatory documentation handling fees, customs clearance, and the Reserve Meds coordination fee. Three- and six-month supply windows reduce per-month logistics overhead and align with the cardiologist's titration check-ins.

On the insurer side, Bupa Arabia, Tawuniya (The Company for Cooperative Insurance), and MedGulf Arabia dominate the private and employer-sponsored market, with the Council of Cooperative Health Insurance (CCHI) governing plan structure. Each insurer handles PCSK9 inhibitor named-patient imports case by case. Some plans reimburse fully when alirocumab is on the formulary, even if not stocked at the patient's hospital; others reimburse a percentage; many require pre-authorisation with the clinical justification letter attached. Cash-pay is the default posture, with reimbursement sought after delivery where the plan permits. Reserve Meds quotes an indicative range at intake and a firm itemised quote after documentation review.

Typical timeline for Praluent in Saudi Arabia

From waitlist submission to first pen in hand, the typical Praluent case in Saudi Arabia 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 SFDA-licensed importer files the PIP application, which clears in 10 to 21 business days for routine cases. In parallel, Reserve Meds aligns US-side specialty pharmacy sourcing, cold-chain qualification, and the shipment plan. Once SFDA approval is issued, US release and shipment add 5 to 10 business days for validated 2 to 8 degree Celsius transit, plus customs clearance into the importer's bonded warehouse or directly to the hospital. The full cycle for an initial 90-day supply is typically 4 to 6 weeks, modestly longer than the comparable UAE EDE cycle. Re-supply on a chronic-therapy cadence aligns with quarterly titration check-ins, and a Praluent case that has cleared its first PIP file moves faster on the second.

What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA PIP package. On institutional letterhead, signed by a SCFHS-licensed physician in cardiology, endocrinology, or lipid-focused internal medicine, the letter typically includes diagnosis with ICD-10 coding (HeFH, HoFH, established ASCVD, or a combination), severity markers including LDL-C at baseline and on current therapy, full prior-therapy history (statin class and dose tried, statin intolerance documentation where applicable, ezetimibe trial, bempedoic acid trial where relevant), the

clinical rationale for PCSK9 inhibitor therapy now, the rationale for alirocumab specifically rather than evolocumab, the proposed dosing plan (75 mg Q2W or 300 mg Q4W starting dose with up-titration to 150 mg Q2W if LDL-C response is inadequate at 8 weeks; the HoFH-specific 150 mg Q2W regimen; the apheresis-adjunct 150 mg Q2W regimen where applicable), the monitoring plan including LDL-C at 4 to 8 weeks post-initiation, and the patient training plan for subcutaneous self-administration.

The physician confirms their SCFHS license is active for the full requested treatment course, since PIP applications are physician-license-tied. For a pediatric heterozygous FH case, the letter references the pediatric FH evidence base, weight-appropriate considerations, and the dispensing facility's pediatric lipid clinic capability at KFSH&RC, KAMC, or a comparable institution. Because Praluent is chronic therapy with no defined finite course, the letter typically requests a 90-day initial supply with re-supply built into the case management plan.

Common questions about Praluent in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Praluent?

Each insurer assesses PCSK9 inhibitor named-patient imports case by case. Some reimburse in full when alirocumab is on the formulary, even when the local hospital pharmacy does not stock it; some reimburse a percentage; several require pre-authorisation with the clinical justification letter attached. Reserve Meds supplies the documentation set that lets the insurer assess; the claim itself sits with you or your hospital. Cash-pay is the default operating posture, with reimbursement sought after delivery where the plan permits.

Will my SCFHS-licensed cardiologist's letter be sufficient?

Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, KSUMC, and private-sector institutions (HMG, Saudi German, Fakeeh, Dallah) have full signing authority on PIP applications. The institutional pharmacy license is what authorises the dispensing facility to receive the imported drug, and the physician's individual license is the anchor for the clinical justification.

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

The dispensing facility must be a Saudi-licensed pharmacy. Praluent is patient-administered subcutaneously, so once dispensed through a hospital outpatient pharmacy or an SFDA-licensed import pharmacy and after injection-technique training, the patient self-administers at home in the thigh, abdomen, or upper arm with site rotation. 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 clinical trials were 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, and the SCFHS-licensed physician is responsible for adverse-event reporting to the SFDA National Pharmacovigilance Center.

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, the 300 mg every-4-weeks dosing option Praluent offers, and prior treatment response. Reserve Meds does not promote one over the other; the PIP corridor 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 SFDA, and do not replace the Saudi dispensing pharmacy. What we do is orchestrate US-side specialty pharmacy sourcing, prepare the regulatory documentation kit the treating physician needs, coordinate cold-chain international logistics with continuous temperature monitoring, and assign a single named coordinator through the case and through quarterly re-supply. 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 the cardiologist's titration calendar.

Next step

If the cardiologist or lipidologist has recommended Praluent and the Saudi pharmacy supply is not aligned with the 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 SFDA Personal Importation Program requires a SCFHS-licensed physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.