Praluent access in Pakistan: the DRAP named-patient pathway

How families and patients in Pakistan obtain Praluent (alirocumab) for familial hypercholesterolemia and atherosclerotic cardiovascular disease through the Drug Regulatory Authority of Pakistan Personal Use Import framework.

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

Quick orientation

Praluent is the brand name for alirocumab, a fully human IgG1 monoclonal antibody co-developed by Regeneron Pharmaceuticals and Sanofi that binds PCSK9 and raises the density of LDL receptors on hepatocytes, lowering circulating LDL cholesterol. The US FDA first approved Praluent in July 2015 as the first PCSK9 inhibitor on the US market, expanded the label in April 2019 to include cardiovascular risk reduction after acute coronary syndrome based on the ODYSSEY OUTCOMES trial, and has subsequently extended the indication to homozygous familial hypercholesterolemia (HoFH) as an adjunct to other LDL-lowering therapies. Pakistan's familial hypercholesterolemia detection has matured most visibly at Aga Khan University Hospital, which operates a cascade-screening capability for FH families through its lipid clinic and pediatric cardiology service. For Pakistani families whose local pharmacy stocks no PCSK9 inhibitor, or whose treating cardiologist prefers Praluent specifically, the DRAP Special Permission for Personal Use Import is the operative pathway.

Reserved for you.

Why patients in Pakistan reach for Praluent through NPP

Pakistan's specialty pharmaceutical market is cash-pay dominant for advanced therapies, and the PCSK9 inhibitor class sits squarely in that segment. Praluent's registration status in Pakistan is uneven, and even where the SFDA or MOHAP-registered presentations cross over via regional agents, on-shelf availability at the pharmacy a Pakistani family actually walks into is inconsistent. Three structural patterns drive Praluent demand through the named-patient route. First, stocking variability. PCSK9 inhibitors in Pakistan are concentrated in tertiary cardiology and lipid-clinic settings in Karachi, Lahore, and Islamabad. A patient referred from Faisalabad, Multan, Peshawar, or Quetta to start PCSK9 therapy may find that even the major Karachi or Lahore pharmacy does not carry Praluent in stock, with a multi-week reorder lead time.

Second, the FH cohort, particularly the pediatric tail. Familial hypercholesterolemia cascade-screening at AKUH and Shaukat Khanum-affiliated lipid programs has improved detection of children and young adults with LDL-C levels that are unresponsive to statin and ezetimibe alone. For these families, the question is not Praluent versus an alternative; it is PCSK9 therapy or untreated cardiovascular risk in a child. Third, patient and prescriber preference between Praluent and Repatha (evolocumab). Where Repatha is the locally stocked PCSK9 inhibitor, a cardiologist or patient who responded to Praluent in prior treatment or who prefers the 300 mg

every-4-weeks dosing option may want to source Praluent specifically. Reserve Meds is not the filer of choice between the two; we coordinate on the prescription written.

The DRAP Personal Use Import pathway for Praluent

The Drug Regulatory Authority of Pakistan (DRAP), established in 2012 under the DRAP Act and reporting to the Federal Ministry of National Health Services, Regulations and Coordination, regulates the import of medicines through its Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered or stocked-but-unavailable medicines required by a specific patient, DRAP issues a Special Permission, commonly referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES) portal, an electronic application channel that lets the applicant, the hospital pharmacy, and DRAP communicate digitally.

For Praluent the clinical justification angle is lipid- and indication-specific. A complete application typically includes:

- A clinical justification letter on hospital letterhead from the treating cardiologist, lipidologist, or internal medicine physician with lipid-clinic experience, documenting the FDA-approved on-label indication: adult HeFH, adult HoFH (as adjunct), adult ASCVD requiring additional LDL-C lowering, or adult cardiovascular risk reduction after acute coronary syndrome
- Lipid-panel results documenting LDL-C trajectory on maximally tolerated statin therapy with or without ezetimibe; for FH cases, genetic testing or clinical-diagnostic criteria documentation (Dutch Lipid Clinic Network or Simon Broome criteria), often generated through the AKUH FH cascade-screening capability for affected family clusters
- A recent prescription specifying brand name (Praluent), generic name (alirocumab), presentation (75 mg pre-filled pen, 150 mg pre-filled pen, or 300 mg presentation for monthly dosing), quantity, and dosing schedule
- The treating physician's PMDC license verification
- The patient identifier: CNIC for adult patients, B-Form for minors, passport for foreign nationals receiving treatment in Pakistan
- Product details: brand name, generic name (INN), manufacturer Regeneron Pharmaceuticals (Tarrytown, NY), strength, dosage form, quantity, and batch number where available
- The destination dispensing facility license (hospital pharmacy license for institutional dispensing)
- A manufacturer or authorized distributor letter confirming the product is genuine and was sourced through the legitimate US specialty pharmacy supply chain
- The chain-of-custody plan from the US source through international shipment to the dispensing facility, including 2 to 8 degree Celsius cold-chain handling with continuous temperature monitoring

Routine personal-use cases typically clear in 4 to 8 weeks from a complete submission. Complex cases, including pediatric FH cases that involve additional documentation review for weight-and-age verification and cascade-screening family-history documentation, can extend to 10 to 16 weeks. Reserve Meds plans on the longer end and treats any faster turnaround as upside.

Where Praluent gets dispensed in Pakistan

Praluent is a refrigerated biologic that the patient or caregiver self-administers by subcutaneous injection after physician or nurse training. The dispensing facilities in Pakistan with the import pharmacy infrastructure, PMDC-licensed cardiology and lipidology rosters, and cold-chain capability for a 2 to 8 degree Celsius biologic are concentrated in Karachi, Lahore, and Islamabad. Aga Khan University Hospital in Karachi, with its lipid clinic, pediatric cardiology service, and FH cascade-screening capability, is a natural home for the Praluent case. AKUH's pharmacy network operates 24/7 with temperature-controlled storage. Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore, while best known for oncology, has an established import pharmacy workflow that supports cardiology biologics where the referring physician is at SKMCH&RC or a partnered institution. Indus Hospital and Health Network in Karachi, Liaquat National Hospital in Karachi, the Pakistan Kidney and Liver Institute (PKLI) in Lahore, the Combined Military Hospitals network at CMH Rawalpindi and CMH Lahore, and Shifa International Hospital in Islamabad each operate import pharmacies that can serve as the dispensing facility.

For pediatric FH patients aged 10 to 17 who meet the prescribing context, the pediatric cardiology services at AKUH and the Children's Hospital and Institute of Child Health in Lahore are the natural homes. Smaller clinics outside Karachi, Lahore, and Islamabad typically partner with a DRAP-licensed specialty importer based in Karachi or Lahore that handles the OIES filing, FBR Customs clearance, and chain-of-custody documentation, and arranges dispensing through one of the major-city tertiary facilities.

Real cost picture for Praluent in Pakistan

Reserve Meds quotes Pakistani patients in US dollars and accepts USD wire transfers from any USD-accessible source, including overseas relatives. The Pakistani Rupee has been volatile across recent years, with the USD to PKR rate in the 278 to 280 range in May 2026 (USD 1 = PKR 278.67 on 8 May 2026; PKR 278.9 to 279.95 on 9 May 2026), and Pakistan's annual CPI inflation rose to 10.9 percent in April 2026. Quoting in USD insulates the patient from intra-case currency drift over the years of chronic therapy a FH or ASCVD patient typically continues on Praluent.

The US wholesale acquisition cost for Praluent was reset by Sanofi and Regeneron in February 2019 to approximately USD 5,850 per year for the 75 mg and 150 mg strengths, a 60 percent reduction from the prior USD 14,625 list. The order-of-magnitude reference for international named-patient sourcing is therefore approximately USD 5,800 to USD 6,500 per year at US list, before specialty pharmacy markup, cold-chain logistics, customs, and coordination overhead. International 2 to 8 degree Celsius cold-chain logistics from the US source to a Karachi or Lahore dispensing facility typically runs USD 400 to USD 1,500 per shipment depending on cycle length and routing. Pakistani families often consolidate funds in USD across multiple senders, pooling resources from relatives in Saudi Arabia, the UAE, the UK, the United States, and Canada before treatment can start. On the insurance side, Adamjee Insurance, Jubilee General Insurance and Jubilee Life Insurance, EFU General Insurance, State Life Insurance Corporation, IGI Insurance, and Pak-Qatar Family Takaful each assess named-patient imports case by case, but coverage for unregistered specialty drugs is uncommon. The realistic default is cash-pay.

Typical timeline for Praluent in Pakistan

For an established FH or ASCVD patient with confirmed clinical or genetic diagnosis, lipid panels on maximally tolerated statin therapy, and a cardiology or lipidology referral, the typical end-to-end cycle is 6 to 10 weeks. The DRAP NOC step generally runs 4 to 8 weeks, with complex pediatric or HoFH cases potentially extending. US-side sourcing through a specialty pharmacy partner with biologic export capability adds 1 to 2 weeks. International 2 to 8 degree Celsius cold-chain transit with data-logger inclusion, FBR Customs clearance at Karachi seaport or Karachi, Lahore, or Islamabad airports, and final delivery to the dispensing hospital pharmacy are typically 5 to 8 days for cold-chain biologics. Reserve Meds plans logistics to a major-city dispensing facility and works with the family on the in-country last mile. Recurring fills on the 75 mg or 150 mg every-two-weeks regimen or the 300 mg monthly regimen run faster once the first fill is complete and the file is on record. Timelines are typical ranges, not promises.

What your physician needs to provide

The clinical justification letter for Praluent is the centerpiece of the DRAP package. For this product the letter typically includes:

- The confirmed indication: adult HeFH, adult HoFH (as adjunct to other LDL-lowering therapies), adult ASCVD requiring additional LDL-C lowering, or adult cardiovascular risk reduction after acute coronary syndrome
- For FH cases: genetic testing report identifying the pathogenic variant, or clinical-diagnostic criteria documentation (Dutch Lipid Clinic Network or Simon Broome). Where the family has been identified through the AKUH FH cascade-screening capability, the cascade-pedigree documentation supports the case
- Lipid-panel history documenting LDL-C trajectory on maximally tolerated statin therapy with or without ezetimibe, including the response inadequacy that justifies adding a PCSK9 inhibitor
- For ASCVD post-ACS cases: documentation of the qualifying acute coronary syndrome event
- The dosing schedule chosen: 75 mg subcutaneously every 2 weeks, 300 mg subcutaneously every 4 weeks, or 150 mg subcutaneously every 2 weeks; for HoFH cases or HeFH patients undergoing LDL apheresis, 150 mg every 2 weeks
- The monitoring plan: LDL-C measurement 4 to 8 weeks after initiation or dose change to assess response and inform any dose adjustment; injection-site reaction surveillance; vigilance for hypersensitivity reactions; no routine hepatic or hematologic monitoring is required by the label

The treating physician's PMDC license verification anchors the application. Cardiologists, lipidologists, pediatric cardiologists, and internal medicine physicians with lipid-clinic experience at the major tertiary centers all have signing authority on Personal Use Import clinical justification letters.

Common questions about Praluent in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Praluent? Coverage for named-patient imports of specialty biologics is uncommon across Pakistani health plans. Some plans pay a

partial percentage on a case-by-case basis where the drug is on a global formulary equivalent. We supply the documentation the insurer needs to assess the claim; the claim itself is yours or your hospital's to file. The realistic default is cash-pay.

How does the AKUH FH cascade-screening capability help my application? Pakistan's FH detection has improved at AKUH through systematic cascade screening of first-degree relatives in known FH families. If your family has been identified through this pathway, the cascade-pedigree documentation strengthens the clinical justification letter materially, particularly for pediatric or young-adult cases where genetic confirmation is in progress. Reserve Meds will work with the AKUH pediatric cardiology or lipid clinic on integrating that documentation into the DRAP package.

Our family pools funds across Pakistan, the Gulf, and the UK. How does Reserve Meds handle that? Reserve Meds quotes in USD and accepts USD wire transfers from any USD-accessible source. Pakistan's diaspora remittance pattern is well-established, and many families consolidate funds across overseas relatives before treatment can start. The transparent USD quote on the firm-quote document lets you plan funding before contacting us.

Is there a competitor or alternative? The principal class competitor is evolocumab (Repatha), an Amgen PCSK9 monoclonal antibody with a similar mechanism and outcomes profile (FOURIER trial for Repatha, ODYSSEY OUTCOMES for Praluent). Inclisiran (Leqvio, Novartis), a small interfering RNA therapy targeting PCSK9 mRNA, offers a twice-yearly dosing alternative after initial loading. Reserve Meds does not promote one over the other; the named-patient pathway supports either based on the prescription written.

Can Praluent be self-administered at home? Yes. The 75 mg and 150 mg pre-filled pens, and the 300 mg presentation, are designed for patient or caregiver self-administration into the thigh, abdomen, or upper arm with site rotation between injections. We coordinate injection training with your prescriber prior to first shipment. The dispensing facility must still be Pakistani-licensed; the carton is handed to the patient from the hospital pharmacy or specialty importer pharmacy, and the patient administers at home.

What is the safety profile? 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.

Where Reserve Meds fits in Praluent cases

Reserve Meds is a US-based concierge coordinator. We do not replace your cardiologist or lipidologist, do not replace DRAP, and do not replace the dispensing hospital pharmacy or the in-country importer. For Praluent specifically we orchestrate the US-side sourcing through a licensed specialty pharmacy with biologic export capability, prepare the regulatory documentation kit your physician needs for the DRAP Personal Use Import filing through OIES (FH or ASCVD indication letter template, lipid-panel summary, dosing schedule, monitoring plan, cascade-screening documentation where available), coordinate the international 2 to 8 degree Celsius cold-chain logistics with continuous temperature monitoring and data-logger inclusion to Karachi, Lahore, or Islamabad, and run a single named coordinator throughout the case in English and Urdu. We do not coordinate off-label use. For FH families pursuing chronic therapy over years, we structure recurring fill cadence so the next shipment is on its way before the current carton runs out.

Next step

If your cardiologist or lipidologist has decided Praluent is the right next step for your FH or ASCVD case and local stocking or pricing is the bottleneck, the named-patient pathway through DRAP 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 and to the dispensing hospital pharmacy.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›
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