Repatha access in Pakistan: the DRAP Personal Use Import pathway

How Pakistani families with familial hypercholesterolemia and patients with established cardiovascular disease obtain Repatha (evolocumab) through the Drug Regulatory Authority of Pakistan named-patient pathway.

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

Quick orientation

Repatha is the Amgen brand of evolocumab, a fully human IgG2 monoclonal antibody PCSK9 inhibitor approved by the US FDA in August 2015 as an adjunct to maximally tolerated statin therapy for adults with heterozygous and homozygous familial hypercholesterolemia (FH) and clinical atherosclerotic cardiovascular disease. The cardiovascular risk reduction indication based on the FOURIER trial was added in December 2017. The pediatric homozygous FH indication was extended in 2017, and in September 2021 the FDA approved Repatha for pediatric heterozygous FH from age 10 and older and lowered the HoFH pediatric age threshold to 10 years. Familial hypercholesterolemia detection in Pakistan is limited but not absent: cardiology services at Aga Khan University Hospital and at major cardiac referral centers do see FH families through their referral networks, and post-MI secondary prevention is a broader indication-of-record. Pakistani families seek authentic Amgen Repatha through the Drug Regulatory Authority of Pakistan Special Permission framework, also known as the Personal Use Import NOC.

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Why Pakistani families reach for Repatha through NPP

Three patterns of access gap operate in Pakistan's specialty market. For Repatha the dominant pattern is the first: registered but not consistently stocked. Repatha is approved in more than 60 countries globally, and Amgen has a regional commercial footprint, but PCSK9 inhibitors in Pakistan are still concentrated in tertiary cardiology centers and a narrow set of private specialty pharmacies in Karachi, Lahore, and Islamabad. A family in a tier-2 city or in a Gulf-adjacent district can be many hours from any pharmacy that actually carries Repatha. For the chronic indefinite therapy that PCSK9 inhibition requires, sporadic local stocking is operationally incompatible with the disease.

Three structural patient profiles drive Repatha inquiries. First, the familial hypercholesterolemia cohort, particularly pediatric HeFH and HoFH patients aged 10 and older, where LDL-C is unresponsive to statin plus ezetimibe alone and the clinical choice is Repatha or untreated risk. Cousin marriage and large family pedigrees in parts of Pakistan can concentrate the FH allele in identifiable families once a tertiary cardiology service screens the kindred. Second, the post-myocardial infarction secondary prevention cohort, where the FOURIER trial regimen on a continuous validated supply chain is the rationale. Third, price accessibility: Amgen reduced US WAC by 60 percent in October 2018 and launched the AmgenNow direct-to-patient program at approximately USD 239 per month in 2025, which positions Repatha at the accessible end of the

biologic price spectrum and makes the cross-border quote more achievable for Pakistani families than other PCSK9-inhibitor or RNAi alternatives.

The DRAP Personal Use Import pathway for Repatha

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For an FDA-approved medicine required for a specific named patient outside routine local stocking, the agency issues a Special Permission (Personal Use Import NOC). Applications are filed through DRAP's Online Import and Export System (OIES) by the institutional pharmacy at a tertiary hospital or by a DRAP-licensed specialty importer in Karachi or Lahore.

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

- A clinical justification letter from the treating cardiologist (or, for pediatric FH cases, a pediatric cardiologist or lipidologist) confirming the FDA-aligned indication: HeFH or HoFH with documented LDL-C uncontrolled on maximally tolerated statin plus ezetimibe, or clinical atherosclerotic cardiovascular disease requiring additional LDL-C lowering, or established cardiovascular disease for the CV risk reduction indication
- For FH cases, genetic testing where available or clinical FH diagnostic criteria (Dutch Lipid Clinic Network, Simon Broome) with the family pedigree if relevant
- The treating physician's PMDC license verification, with FCPS Pakistan specialist registration in cardiology or pediatric cardiology where applicable
- The patient identifier: CNIC for adult patients, B-Form for pediatric patients (ages 10 and older for FH)
- Product details: Repatha, the specific presentation requested (140 mg single-dose SureClick autoinjector, 140 mg single-dose prefilled syringe, or 420 mg single-dose Pushtronex on-body infusor), manufacturer Amgen Inc., country of origin, pack size, and quantity to cover a defined course of therapy
- The destination dispensing facility's hospital pharmacy license, confirming the receiving pharmacy is licensed to handle imported pharmaceuticals and operates 2 to 8 degrees Celsius cold-chain storage
- A manufacturer or authorised distributor letter confirming the product is genuine Amgen Repatha sourced through the legitimate US specialty-pharmacy chain
- A validated cold-chain plan from the US source through international air freight to Karachi, Lahore, or Islamabad with continuous temperature logging

Routine personal-use cases typically clear in four to eight weeks from a complete submission. The 30-day room-temperature stability window once Repatha is removed from refrigeration provides usable transit slack on cross-border lanes; Reserve Meds 3PL partners route Repatha as a standard cold-chain biologic with temperature loggers in every parcel.

Where Repatha gets dispensed in Pakistan

Repatha is a refrigerated biologic monoclonal antibody. Dispensing requires 2 to 8 degrees Celsius storage and a pharmacy with continuous-temperature cold-chain capability. The institutions that handle named-patient imports of refrigerated biologics as established workflow

are concentrated in Karachi, Lahore, and Islamabad. The natural homes for Repatha dispensing are the cardiology services at Aga Khan University Hospital (AKUH) in Karachi (24/7 temperature-controlled pharmacy network, with the broadest cardiology and pediatric cardiology footprint in Pakistan), Liaquat National Hospital in Karachi, the Indus Hospital and Health Network in Karachi, the Combined Military Hospitals (CMH) network at CMH Rawalpindi and CMH Lahore (with established cardiology programs), and Shifa International Hospital in Islamabad.

For pediatric FH cases the natural homes are the pediatric cardiology services at AKUH and the Children's Hospital and Institute of Child Health in Lahore. Pakistan Kidney and Liver Institute (PKLI) in Lahore is also a relevant partner for patients with concurrent renal disease where PCSK9 inhibition is being considered. Families in Peshawar, Quetta, Multan, Faisalabad, or smaller cities typically route to a Karachi, Lahore, or Islamabad hospital pharmacy for receipt and then continue follow-on care under their local treating physician. Self-administration by the patient or caregiver after appropriate training is the labeled mode; the autoinjector and the on-body infusor are both designed for that.

Real cost picture for Repatha in Pakistan

Amgen reduced US wholesale acquisition cost for Repatha by 60 percent in October 2018, from approximately USD 14,100 per year to USD 5,850 per year. Current WAC is approximately USD 572.70 per 140 mg autoinjector or prefilled syringe, translating to roughly USD 6,875 per year on the 140 mg every-two-weeks regimen or a similar annual cost on the 420 mg monthly regimen. The AmgenNow direct-to-patient program (US only) offers cash-paying US patients access at approximately USD 239 per month, or roughly USD 2,868 per year; this program does not extend to international named-patient sourcing.

The Pakistani rupee has been volatile across the last several years; as of May 2026 the USD to PKR rate sits in the 278 to 280 range, with April 2026 CPI inflation at 10.9 percent. At current exchange rates a USD 6,875 annual drug cost translates to roughly PKR 1.9 million, and the rupee figure can move materially over a single quote-to-shipment cycle. Repatha is at the accessible end of the biologic spectrum for Pakistani families paying out of pocket, and the cross-border quote can be competitive with the local stocked price in markets where the drug is technically registered but unavailable in the patient's city.

Because PKR has been volatile historically and inflation is again rising, Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source. International cold-chain logistics for Repatha run in the USD 500 to USD 1,000 range per shipment depending on quantity and route, with the 30-day room-temperature stability providing operational slack. DRAP fees and FBR Customs charges are nominal relative to the drug itself. The Reserve Meds coordination fee is itemised separately on every firm quote. On insurance, Adamjee, Jubilee, EFU, State Life, IGI, and Pak-Qatar each assess named-patient imports case by case; some plans reimburse a percentage for cardiology biologics on case-by-case review, but the realistic default is cash-pay.

Typical timeline for Repatha in Pakistan

For an established cardiology patient with documented FH genotype or LDL-C history, current statin plus ezetimibe regimen confirmation, and a major-city cardiologist or pediatric cardiologist, the typical end-to-end cycle is 6 to 10 weeks. The DRAP Special Permission step generally runs 4 to 8 weeks for routine cases on the OIES portal. US-side sourcing through

Amgen's authorised specialty-pharmacy channel adds approximately 1 to 2 weeks. International cold-chain air freight and FBR Customs clearance at Karachi, Lahore, or Islamabad airport are typically 3 to 5 days under qualified passive shippers with temperature logging; the 30-day room-temperature stability window absorbs typical customs holds without excursion concern. Recurring fills every two weeks (140 mg) or once monthly (420 mg) are the cadence after first cycle. Timelines are presented as typical ranges, not promises; specific dates are confirmed at firm-quote issuance.

What your physician needs to provide

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

- For familial hypercholesterolemia, documentation of HeFH or HoFH using clinical criteria (Dutch Lipid Clinic Network, Simon Broome) or genetic testing where available, with current LDL-C levels and prior therapy history confirming inadequate response to maximally tolerated statin plus ezetimibe
- For atherosclerotic cardiovascular disease, documentation of clinical ASCVD with prior MI, stroke, peripheral arterial disease, or revascularisation, with current LDL-C and prior therapy history
- For pediatric FH cases (ages 10 and older), pediatric weight, BMI percentile, family pedigree where relevant, and pediatric cardiology specialist supervision
- The dosing plan: 140 mg subcutaneously every 2 weeks or 420 mg subcutaneously once monthly for adult primary hyperlipidemia or CV risk reduction; for adult HoFH, 420 mg monthly with optional titration to 420 mg every 2 weeks after 12 weeks if response is inadequate; equivalent dosing for pediatric HeFH and pediatric HoFH
- The monitoring plan: LDL-C measurement 4 to 8 weeks after initiation and dose titration, then periodically per the treating clinician's protocol; no routine liver function or muscle enzyme monitoring required by the label, in contrast to high-intensity statin therapy; injection-site reaction monitoring; hypersensitivity awareness
- The injection-training plan: confirmation that the patient or caregiver will receive appropriate training on the autoinjector or on-body infusor before first self-administration; Reserve Meds coordinates training with the patient's home-country prescriber prior to first shipment
- The pharmacovigilance commitment to report adverse events through the DRAP Pharmacovigilance Centre as part of the post-import obligation

PMDC-licensed cardiologists, pediatric cardiologists, and lipidologists at AKUH, Liaquat National, Indus, CMH Rawalpindi or Lahore, Shifa International, and Children's Hospital Lahore hold full signing authority on Special Permission applications.

Common questions about Repatha in Pakistan

Is Repatha registered in Pakistan? Repatha is approved in more than 60 countries globally, and Amgen has a regional commercial presence. Pakistani stocking depth varies, and even in countries where the drug is technically registered, on-the-ground availability is often limited to a

small number of tertiary cardiology centers. The DRAP Special Permission pathway is the lawful route for any patient where local stocking does not meet the clinical timeline.

Will Adamjee, Jubilee, EFU, or State Life cover Repatha? Coverage for named-patient imports of cardiology biologics varies. Some plans reimburse a percentage on case-by-case review, particularly when the documented FH or ASCVD indication aligns with the insurer's formulary equivalents. The realistic default is cash-pay. We supply the documentation set the insurer needs to assess; the claim itself is yours or your hospital's to file.

How does Repatha compare with Praluent or Leqvio? Praluent (alirocumab, Regeneron and Sanofi) is a PCSK9 monoclonal antibody with a similar mechanism, dosing schedule, and cardiovascular outcomes profile. Leqvio (inclisiran) is a small interfering RNA therapy targeting PCSK9 mRNA, with a twice-yearly maintenance dosing schedule after initial loading. The choice among these is a clinical decision for your cardiologist, not Reserve Meds. We coordinate Repatha for patients whose physician has selected evolocumab.

Can my child receive Repatha? Yes, from age 10 and older for pediatric HeFH and pediatric HoFH per the September 2021 FDA label extension. Pediatric cardiology supervision at AKUH, Children's Hospital Lahore, or another tertiary pediatric service is the standard pathway.

What is the safety profile? Repatha is generally well tolerated. Most common adverse reactions in clinical trials were nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection-site reactions. Serious hypersensitivity reactions including angioedema have been reported and require discontinuation. The FDA label does not require routine liver function or muscle enzyme monitoring, unlike high-intensity statin therapy.

Can the medicine be delivered to our home? The dispensing facility must be a Pakistan-licensed pharmacy with cold-chain capability. After dispensing, self-administration at home is the labeled mode; cold-chain integrity from the dispensing pharmacy to the patient's home is the patient's clinic's responsibility, and Reserve Meds coordinates injection training with the home-country prescriber before first shipment.

Where Reserve Meds fits in Repatha cases

Reserve Meds is a US-based concierge coordinator. We do not replace your cardiologist or pediatric cardiologist, do not replace DRAP, and do not replace the dispensing hospital pharmacy or in-country importer. For Repatha specifically we orchestrate US-side sourcing through Amgen's authorised specialty-pharmacy channel, the regulatory documentation kit your physician needs (FH or ASCVD letter template, dosing reference by indication, monitoring plan summary, injection-training coordination, DRAP pharmacovigilance reference), validated cold-chain logistics with continuous temperature monitoring, and a single named coordinator. FH genotype or clinical criteria documentation (for FH cases) or ASCVD history (for CV risk reduction cases), current LDL-C and prior-therapy history, and pediatric specialist sign-off (for under-18 cases) are mandatory intake artefacts. Repatha integrates with Reserve Meds 3PL partners on the standard refrigerated-biologics SOP.

Next step

If your cardiologist has decided Repatha is the right next step for FH, ASCVD, or CV risk reduction and DRAP Special Permission 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.

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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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