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Repatha access in India: the CDSCO Rule 36 named-patient pathway

How families in India obtain Repatha (evolocumab) for familial hypercholesterolemia in adults and pediatric patients aged 10 and older, and for cardiovascular risk reduction in established atherosclerotic disease, through the CDSCO Rule 36 personal-import permit.

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

Quick orientation

Repatha is the Amgen brand of evolocumab, a fully human monoclonal antibody targeting PCSK9 that lowers LDL cholesterol by raising hepatic LDL-receptor density. The FDA-approved indications cover adults with heterozygous and homozygous familial hypercholesterolemia (HeFH and HoFH), adults with established atherosclerotic cardiovascular disease (ASCVD) requiring additional LDL-C lowering, cardiovascular risk reduction in adults with established cardiovascular disease, and pediatric patients aged 10 and older with HeFH or HoFH. Repatha holds CDSCO approval in India, and Amgen partners with local distributors. Retail availability is uneven outside metropolitan cardiology referral centres, which is the typical pattern for the families who reach for the named-patient route. Indian FH detection has improved over the past several years through cascade screening programmes at tertiary cardiology centres, and that improvement is bringing more families to the question of how to get a PCSK9 inhibitor stocked and continued. The route runs through the CDSCO Rule 36 personal-import permit on Form 12A and Form 12B.

Reserved for you.

Why families in India reach for Repatha through NPP

India faces three patterns of access gap for US originator specialty medicines: registered but not stocked, registered for a different indication, and not registered locally at all. Repatha sits squarely in the first pattern. Amgen holds CDSCO approval and Repatha is in more than sixty country registrations globally, so the gap in India is not registration. The gap is stocking depth. PCSK9 inhibitors are still concentrated in tertiary cardiology centres and a narrow set of private specialty pharmacies in many Indian metros. A patient in a tier 2 city, or a family in a Gulf emirate handling logistics for a parent in India, can be many hours from any pharmacy that actually carries Repatha at the strength and presentation needed.

The familial hypercholesterolemia cohort is the central pattern. India's FH detection has been improving through cascade screening programmes at AIIMS, Apollo, CMC Vellore, and other tertiary cardiology centres, and pediatric FH detection is rising in parallel. The FDA pediatric indication for HeFH and HoFH at age 10 and older means more Indian children are clinically eligible for PCSK9 inhibition than the local stocking footprint reliably supports. Repatha is also at the more accessible end of the biologic-monoclonal-antibody price spectrum after Amgen's October 2018 list-price reduction of 60 percent, and post-MI secondary-prevention patients seeking the documented FOURIER-trial regimen on a continuous, validated supply chain are

another well-aligned cohort. Reserve Meds does not coordinate Repatha for off-label use; all named-patient cases are screened against the FDA label indication of record.

The CDSCO named-patient pathway for Repatha

The legal foundation for personal import of medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug for the exclusive personal use of a named patient, even where local registration exists, when the local supply chain cannot meet that patient's documented need. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

For Repatha the clinical-justification angle is indication-specific and, for FH cases, often genetic. The Reserve Meds documentation kit asks the prescribing physician to name which FDA-approved indication applies, to document LDL-C history on maximally tolerated statin and ezetimibe therapy, and to confirm the dose schedule (140 mg every 2 weeks, or 420 mg once monthly; the 420 mg monthly schedule for HoFH may titrate up to 420 mg every 2 weeks after 12 weeks if response is inadequate). The application typically includes:

- A clinical justification letter naming the indication (HeFH, HoFH, established ASCVD requiring additional LDL-C lowering, or cardiovascular risk reduction in established CVD), the LDL-C trajectory on maximally tolerated statin plus ezetimibe, and for FH cases the genetic or clinical FH diagnosis (DLCN criteria or genetic confirmation of LDLR, APOB, or PCSK9 mutation where available)
- The treating physician's NMC registration number and a copy of state council registration where required
- A patient identifier and supporting medical records, including the lipid panel history
- Product details: Repatha, evolocumab, the specified presentation (140 mg SureClick autoinjector, 140 mg prefilled syringe, or 420 mg Pushtonex on-body infusor), manufacturer Amgen, quantity (not to exceed one hundred average doses per application)
- The dispensing facility's drug licence
- A chain-of-custody plan from an authorised US source to the dispensing pharmacy in India

CDSCO's published guidance states the Form 12B permit issues on a priority basis, typically within one to two days for routine applications where the documentation is complete. In practice families plan for a two to four week window from physician decision to dispensed medicine, because the bulk of the elapsed time is upstream documentation assembly and downstream cold-chain logistics rather than the regulator stamp.

Where Repatha gets dispensed in India

Repatha is a refrigerated biologic monoclonal antibody. The dispensing facility must hold a valid drug licence and must be able to receive and store the product at 2 to 8 degrees Celsius. Tertiary cardiology services and large hospital pharmacies routinely handle this category, and PCSK9 inhibitor stocking is concentrated at exactly those institutions. Centres with established cardiology, lipidology, and import-pharmacy infrastructure include the All India Institute of

Medical Sciences (AIIMS) in New Delhi, Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis Memorial Research Institute in Gurgaon and the Fortis Mulund, Bangalore, and Kolkata sites, Medanta in Gurgaon with its Heart Institute, Kokilaben Dhirubhai Ambani Hospital in Mumbai, MGM Healthcare in Chennai with its tertiary cardiac programme, Christian Medical College (CMC) in Vellore, and Manipal Hospitals in Bangalore.

For pediatric FH cases (HeFH or HoFH at age 10 and older), the natural homes are the pediatric cardiology and lipidology services at AIIMS Delhi, the pediatric programmes at Apollo Chennai and Apollo Delhi, CMC Vellore's pediatric cardiology service, and the pediatric service at Kokilaben Mumbai. Families in tier 2 cities without a local PCSK9-inhibitor centre typically route to one of these centres for the clinical letter and then work with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore for the Form 12A filing and the chain-of-custody documentation. Repatha can be self-administered after training; Reserve Meds coordinates equivalent injection training with the prescribing physician's team prior to first shipment for new patients.

Real cost picture for Repatha in India

Amgen reduced the US list price (wholesale acquisition cost, WAC) of Repatha by 60 percent in October 2018. Current US WAC is approximately USD 572.70 per 140 mg autoinjector or prefilled syringe, which translates to roughly USD 6,875 per year on the 140 mg every 2 weeks regimen and a similar annual cost on the 420 mg monthly regimen. For a biologic monoclonal antibody this is at the accessible end of the price spectrum. The AmgenNow direct-to-patient programme offers US cash-pay patients access at approximately USD 239 per month (roughly USD 2,868 per year); the programme is US-only and does not extend to international patients. RepathaReady (benefits verification and copay assistance) is similarly US-only.

The Indian rupee floats against the US dollar. In May 2026 the USD/INR rate sits in the 94 to 95 range. Monthly drug acquisition at US WAC translates to roughly INR 54,000 on the 140 mg every-2-weeks regimen at the prevailing rate (two autoinjectors per month) or a comparable amount on the 420 mg monthly regimen. International cold-chain logistics for the validated 96-hour transit envelope typically runs at USD 500 to USD 1,000 per shipment (approximately INR 47,000 to INR 95,000), inclusive of insulated shipper, temperature loggers, and customs handover. India's Union Budget 2026-27 customs duty exemptions focus on cancer and rare-disease medicines; the specific HSN code and duty status for any Repatha shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5%.

On the insurance side, Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa handle named-patient imports case by case; none reimburse a Rule 36 personal import as a standard line item. CGHS provides for life-saving and approved medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS) case by case; Repatha's local CDSCO approval is a favourable factor in that assessment. Cash-pay is the default posture for most families. The accessible end of the price spectrum makes long-term affordability more workable than for many other biologics.

Typical timeline for Repatha in India

For a documented FH or ASCVD patient with current LDL-C panels, statin and ezetimibe history, and a prescribing-physician letter, the typical end-to-end cycle is 2 to 4 weeks. CDSCO published guidance puts the Form 12B priority window at 1 to 2 days for complete routine documentation. US-side sourcing through an authorised distributor adds roughly 1 to 2 weeks. International cold-

chain transit and Indian customs clearance at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airport are typically 3 to 5 days inside the unopened-pen stability envelope. Repatha has a 30-day room-temperature stability window (up to 25 degrees Celsius in the original carton) after first removal from refrigeration, which provides usable slack on transit and on the family's home storage. Timelines are presented as typical ranges and not as promises; specific dates are confirmed at firm-quote issuance.

What your physician needs to provide

The clinical justification letter for Repatha is indication-specific and, for FH, often anchored on genetic or DLCN-criteria-clinical diagnosis. For Reserve Meds intake the letter typically includes:

- The FDA-approved indication: adult HeFH or HoFH; adult ASCVD requiring additional LDL-C lowering; cardiovascular risk reduction in adults with established CVD; or pediatric HeFH or HoFH in patients aged 10 years and older
- The LDL-C trajectory: baseline LDL-C, LDL-C on maximally tolerated statin therapy, LDL-C on statin plus ezetimibe, and the documented gap to the goal level appropriate for the patient's risk category
- For FH cases, the diagnostic basis: DLCN clinical criteria scoring, genetic confirmation where available (LDLR, APOB, or PCSK9 mutation), and family-history documentation. For HoFH, the diagnostic workup is typically more complete given the rarity and severity
- For ASCVD cases, documentation of established atherosclerotic cardiovascular disease (prior MI, prior stroke, peripheral arterial disease, prior coronary revascularization)
- The dose schedule: 140 mg subcutaneously every 2 weeks or 420 mg subcutaneously once monthly for primary hyperlipidemia and ASCVD; 420 mg once monthly for HoFH with optional titration to 420 mg every 2 weeks after 12 weeks if response is inadequate
- The monitoring plan: LDL-C measured 4 to 8 weeks after initiation and dose titration, then periodically; vigilance for hypersensitivity reactions including angioedema (which would require discontinuation)
- For pediatric cases (age 10 and older), the weight-adjusted considerations and the family-engagement component of the injection-training plan
- The PvPI adverse-event reporting plan as part of the Pharmacovigilance Programme of India obligation

The treating physician's NMC registration number must appear on the prescription. State-council registration is required for practice in a particular state. Cardiology, lipidology, and pediatric cardiology specialists at AIIMS, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal routinely sign these letters as part of established institutional workflow.

Common questions about Repatha in India

Is Repatha available locally in India already? Yes. CDSCO has approved Repatha and Amgen partners with local distributors. Retail availability is uneven outside metropolitan cardiology referral centres, which is why families in tier 2 cities or with intermittent local stocking look at the cross-border route.

What about my 11-year-old child with HeFH? Repatha is FDA-approved for HeFH and HoFH in pediatric patients aged 10 and older. Reserve Meds intake for pediatric Repatha requires the

FH diagnostic workup (genetic confirmation where available, DLCN clinical criteria, family history) and the pediatric cardiology or lipidology letter.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Repatha? Each plan handles named-patient imports case by case. None reimburse a Rule 36 personal import as a standard line item. Where the case is well-documented FH or ASCVD with statin and ezetimibe failure, some insurers have reimbursed full or partial drug cost. We supply the documentation set that lets your insurer assess the case. Cash-pay is the default posture, and Repatha sits at the more accessible end of the biologic price spectrum.

Will CGHS cover Repatha? CGHS provides for life-saving and approved medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS) case by case. Repatha's CDSCO approval is a favourable factor in that assessment. Check eligibility with your CGHS Wellness Centre.

Should we use Repatha or alirocumab (Praluent)? Both PCSK9 inhibitors are clinically reasonable choices for the same indication set. Selection usually rests on prescriber familiarity, device preference (Repatha offers the 420 mg single-dose monthly on-body infusor), and continuity of supply. Reserve Meds also coordinates Praluent for the on-label indications.

Should we use Repatha or inclisiran (Leqvio)? Inclisiran is a twice-yearly siRNA therapy targeting PCSK9 mRNA. The dosing convenience is real, the clinical setting and prescriber familiarity differ. Selection is clinician-driven.

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. No routine liver function or muscle enzyme monitoring is required by the label, in contrast to high-intensity statin therapy.

Where Reserve Meds fits in Repatha cases

Reserve Meds is a US-based concierge coordinator. We do not replace your cardiologist, lipidologist, or pediatric cardiologist, do not replace CDSCO, and do not replace the local Amgen distribution network or the dispensing pharmacy. For Repatha specifically we orchestrate the US-side sourcing through an authorised distributor, the regulatory documentation kit your physician needs for Form 12A (FH-diagnostic letter template, LDL-C trajectory reference, dose-schedule reference, monitoring plan summary, PvPI reporting reference), international cold-chain logistics within the validated 96-hour envelope with temperature loggers and dual-validated insulated shippers, injection-training coordination with the prescribing team where applicable, and a single named coordinator who carries the family from intake through delivery and into the long-term refill cadence. The accessible end of the biologic price spectrum and the relatively forgiving 30-day room-temperature stability window make Repatha one of the more workable cross-border configurations for an FH family in India.

Next step

If your cardiologist, lipidologist, or pediatric cardiologist has decided Repatha is the right next step for familial hypercholesterolemia or ASCVD and local stocking or continuity is the bottleneck, the Rule 36 personal-import pathway through CDSCO 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.

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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 >
Last medically reviewed: 2026-05-12.