Repatha access in the UAE: the EDE named-patient pathway

How UAE families access Repatha (evolocumab) for familial hypercholesterolemia and established cardiovascular disease through the Emirates Drug Establishment unregistered-medicine import permit, including pediatric FH from age 10.

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

Quick orientation

Repatha is the Amgen brand name for evolocumab, a fully human IgG2 monoclonal antibody that binds proprotein convertase subtilisin/kexin type 9 (PCSK9). By blocking PCSK9, evolocumab raises the density of hepatic LDL receptors on the liver surface and increases the clearance of low density lipoprotein cholesterol from the bloodstream. The US FDA first approved Repatha in August 2015. The current approved indications cover adults with heterozygous familial hypercholesterolemia, adults with homozygous familial hypercholesterolemia, adults with clinical atherosclerotic cardiovascular disease requiring additional LDL-C lowering, cardiovascular risk reduction in adults with established cardiovascular disease (December 2017, based on the FOURIER trial), and pediatric patients aged 10 years and older with heterozygous or homozygous FH (September 2021 expansion). In the UAE Repatha is registered with MOHAP and is available through hospital tenders and a limited number of private pharmacies, but local stocking depth is concentrated in tertiary cardiology centres in Abu Dhabi and Dubai. Families outside the major metros, and FH families requiring continuity of supply for a chronic condition, are the typical named-patient candidates.

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Why patients in the UAE reach for Repatha through NPP

The UAE has a mature pharmaceutical regulatory environment, and the three structural access gaps the framework is built to bridge apply across the catalog: registered but not stocked, registered for a different indication, or not registered at all. Repatha sits in the first category in this market. The drug is registered, and stocking depth in tertiary cardiology centres in Abu Dhabi and Dubai is adequate for established institutional patients, but PCSK9 inhibitor inventory in private pharmacies outside the metros remains uneven. A patient in the Northern Emirates or a smaller emirate, or a family whose cardiologist works at a hospital without an in-house PCSK9 program, can be many kilometres from a pharmacy that actually carries Repatha.

Two patient cohorts drive UAE Repatha demand through the named-patient route. The first is the familial hypercholesterolemia family, particularly pediatric HeFH and HoFH patients aged 10 and older, where LDL-C is unresponsive to maximally tolerated statin therapy plus ezetimibe. For these families the choice is not Repatha versus an alternative; it is Repatha or untreated cardiovascular risk that compounds over decades. When local supply is intermittent, families with means turn to cross-border continuity. The second cohort is the post-myocardial-infarction patient on secondary-prevention therapy who prefers the FOURIER trial regimen (Sabatine et al.,

NEJM 2017) on a validated supply chain. For a biologic monoclonal antibody, Repatha is also at the accessible end of the price spectrum; the AmgenNow direct-to-patient program in the US offers cash-paying patients access at approximately USD 239 per month, which sets a lower price-anchor reference than most international list prices.

The EDE named-patient pathway for Repatha

The federal pathway is the unregistered-medicine import permit, administered through the EDE portal at ede.gov.ae from 29 December 2025 onward under Federal Decree-Law No. 38 of 2024. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when a clinically equivalent locally registered alternative is not suitable or not available on the timeline required, which covers the typical Repatha case where the drug is locally registered but not consistently stocked at the patient's care location.

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

- A clinical justification letter from the treating physician (cardiologist, lipidologist, pediatric lipid specialist, or internist with lipid-disorder credentials) documenting the on-label indication: adult HeFH, adult HoFH, adult ASCVD requiring additional LDL-C lowering, cardiovascular risk reduction in adults with established cardiovascular disease, or pediatric HeFH or HoFH (age 10 and older)
- The patient's diagnostic workup: confirmed FH diagnosis (genetic testing or clinical criteria such as Dutch Lipid Clinic Network or Simon Broome), baseline and most recent LDL-C and total cholesterol, and prior lipid-lowering therapy (maximally tolerated statin, ezetimibe), with documented inadequate response or intolerance where applicable
- The treating physician's UAE medical license (MOHAP, DHA, DOH, or Sharjah Health Authority)
- An anonymised patient identifier where the EDE submission allows
- Product details: Repatha, evolocumab, manufacturer Amgen Inc., the specific presentation requested (140 mg SureClick autoinjector, 140 mg prefilled syringe, or 420 mg Pushtronex on-body infusor with prefilled cartridge), pack count, intended treatment duration
- The destination dispensing facility license number and pharmacy in charge
- A cold-chain plan from the US authorised distributor through the importer to the dispensing pharmacy

Approval timelines for routine cases are typically 5 to 15 business days. Repatha is well-characterised, with established regional registration, so files generally fall within the routine band. Pediatric FH cases with genetic-test documentation move smoothly because the eligibility is unambiguous.

Where Repatha gets dispensed in the UAE

Repatha is a refrigerated biologic. The dispensing facility must hold a UAE pharmaceutical establishment license and a 2 to 8 degrees Celsius cold chain. The UAE institutions that handle named-patient cold-chain imports as established workflow and have established cardiology and lipid services include Cleveland Clinic Abu Dhabi (M42 group), Sheikh Khalifa Medical City in Abu Dhabi (SEHA network, JCI-accredited), American Hospital Dubai (Mayo Clinic Care

Network), King's College Hospital London Dubai, Mediclinic City Hospital in Dubai Healthcare City, and the larger NMC Healthcare sites. The complex cardiology programs at Cleveland Clinic Abu Dhabi and the cardiology and lipid services across the network are the natural homes for the Repatha patient cohort. Pediatric FH cases route to facilities with pediatric subspecialty services, including SKMC's pediatric service, American Hospital Dubai's pediatric service, and Cleveland Clinic Abu Dhabi's pediatric service.

The 30-day room-temperature stability window (up to 25 degrees Celsius in the original carton) after removal from refrigeration gives Repatha a generous operational reserve for the patient's home use, which makes it well-suited to the family-led self-administration model the molecule is designed for. Smaller clinics route through a Dubai- or Abu Dhabi-based specialty importer for the EDE permit and cold-chain customs clearance.

Real cost picture for Repatha in the UAE

Amgen reduced the US wholesale acquisition cost of Repatha by 60 percent in October 2018, from approximately USD 14,100 per year to USD 5,850 per year. The current 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-two-weeks regimen and a similar annual cost on the 420 mg monthly regimen. Through the AmgenNow direct-to-patient program launched in 2025, cash-paying US patients can access Repatha at approximately USD 239 per month, or roughly USD 2,868 per year, although that program is US-only.

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD, so the US WAC annual cost translates to roughly AED 25,200 per year. International cold-chain logistics typically runs USD 500 to USD 1,200 per shipment (approximately AED 1,800 to AED 4,400), reflecting validated 2 to 8 degrees Celsius packaging, temperature loggers, and customs clearance under permit. UAE customs and EDE permit fees are nominal relative to the drug cost. For a biologic monoclonal antibody, Repatha is at the accessible end of the price spectrum, which materially lowers the financial barrier compared with most specialty oncology or rare-disease cases. On insurance: Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, and Orient each assess named-patient imports case by case. Several reimburse partially for PCSK9 inhibitor therapy when the patient meets formulary criteria (typically documented FH or ASCVD with inadequate response to maximally tolerated statin and ezetimibe).

Typical timeline for Repatha in the UAE

For an established FH or post-MI patient with a clean clinical-justification letter, the typical end-to-end cycle is 3 to 5 weeks. The EDE permit step generally runs 5 to 15 business days. US-side sourcing through authorised Amgen distributors adds 3 to 7 days; supply has been stable since launch in 2015 with no nationally reported allocation events, so this segment is rarely the bottleneck. International cold-chain transit and UAE customs clearance under the import permit are typically 3 to 7 days, well inside the 30-day room-temperature stability envelope. Cold-chain biologic shipments add 2 to 3 days versus an ambient-controlled product. Pediatric FH cases that require institutional sign-off at the dispensing facility for first-time pediatric pharmacy file may add 1 to 2 weeks to the front-end cycle.

What your physician needs to provide

The clinical justification letter is the centre of the EDE package. For Repatha the letter typically includes:

- The patient's confirmed indication: adult HeFH, adult HoFH, adult ASCVD requiring additional LDL-C lowering, cardiovascular risk reduction in adults with established cardiovascular disease, or pediatric HeFH or HoFH (age 10 and older)
- The diagnostic workup: genetic testing (where applicable for FH), clinical FH criteria (Dutch Lipid Clinic Network score or Simon Broome), baseline and most recent LDL-C and total cholesterol
- Prior lipid-lowering therapy: maximally tolerated statin therapy, ezetimibe, and any prior PCSK9 inhibitor exposure
- The dosing plan, by indication:
    - Adult primary hyperlipidemia including HeFH and ASCVD with CV risk reduction: 140 mg subcutaneously every 2 weeks, OR 420 mg subcutaneously once monthly
    - Adult HoFH: 420 mg subcutaneously once monthly; after 12 weeks the dose may be increased to 420 mg every 2 weeks if a clinically meaningful response is not achieved
    - Pediatric HeFH (ages 10 and older): 140 mg every 2 weeks, OR 420 mg once monthly
    - Pediatric HoFH (ages 10 and older): 420 mg once monthly, with the option to titrate to 420 mg every 2 weeks after 12 weeks
- The monitoring plan: LDL-C measured 4 to 8 weeks after initiation or dose change, then periodically; no routine liver function or muscle enzyme monitoring is required by label (in contrast to high-intensity statin therapy); injection-site reaction monitoring; counseling on hypersensitivity reactions including angioedema which is a labeled concern requiring discontinuation

The treating physician's UAE license must match the emirate of the dispensing facility. For pediatric FH cases, the dispensing facility's pediatric pharmacy team typically signs the receipt.

Common questions about Repatha in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Repatha? Each insurer assesses named-patient imports case by case. PCSK9 inhibitor coverage in regional plans typically requires documented FH or ASCVD with inadequate response to maximally tolerated statin and ezetimibe. We supply the documentation; we do not promise coverage.

My child is 11 with HeFH. Is Repatha approved at that age? Yes. The FDA approved Repatha for pediatric HeFH and HoFH patients aged 10 and older in September 2021. Documentation of the genetic FH diagnosis and the inadequate response to maximally tolerated statin and ezetimibe is part of the file.

Can Repatha be self-administered? Yes. The 140 mg SureClick autoinjector and the 420 mg Pushtronex on-body infusor are both designed for patient or caregiver self-administration after training. The patient's treating physician or the dispensing pharmacy provides injection training before the first dose; the 30-day room-temperature window allows the family to store opened cartons at home conveniently.

What is the safety profile? Repatha is generally well tolerated. The 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.

Why Repatha versus alirocumab (Praluent) or inclisiran (Leqvio)? Alirocumab (Regeneron/Sanofi) is a class competitor with a similar mechanism, dosing schedule, and cardiovascular outcomes profile. Inclisiran is a small interfering RNA therapy targeting PCSK9 mRNA with twice-yearly dosing after initial loading. Repatha offers a 420 mg single-dose monthly on-body infusor that alirocumab does not. Choice is a clinician-led decision based on prior experience, prescriber familiarity, device preference, and supply continuity.

What is the typical course duration? Indefinite. Repatha is chronic therapy. The FOURIER trial dosed patients for a median of 2.2 years and the OSLER open-label extension followed patients for more than 5 years on continuous therapy.

Where Reserve Meds fits in Repatha cases

Reserve Meds is a US-based concierge coordinator. We do not replace your cardiologist or lipidologist, do not replace the EDE, and do not replace the dispensing pharmacy. For Repatha specifically we orchestrate US-side sourcing through authorised Amgen distributors (McKesson, AmerisourceBergen, Cardinal Health) and the specialty-pharmacy network (CVS Specialty, Accredo, Optum Specialty), the regulatory documentation kit your physician needs (FH or ASCVD indication template, dosing reference by indication and age, monitoring plan summary), validated 2 to 8 degrees Celsius cold-chain logistics under chain-of-custody with a 96-hour transit envelope, and a single named coordinator through the case. We coordinate injection training with the patient's home-country prescriber prior to first shipment so the family is ready when the medicine arrives. We do not coordinate off-label use, and intake is screened against the FDA label indications of record.

Next step

If your cardiologist or lipidologist has decided Repatha is the right next step and local stocking is the bottleneck, the EDE named-patient pathway 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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