Leqvio access in the United Arab Emirates: the EDE named-patient pathway

How UAE adults pursue inclisiran, the Novartis small-interfering-RNA targeting PCSK9, when statins and ezetimibe have not delivered the LDL-cholesterol target the cardiology team expected.

Last reviewed 2026-05-12 by the Reserve Meds clinical and regulatory team. This page combines the UAE country research module with the Leqvio drug module to describe the path families actually walk.

Quick orientation

Leqvio (inclisiran) is a small-interfering RNA (siRNA) therapeutic that suppresses PCSK9 synthesis in hepatocytes. It is developed by Novartis (originally Alnylam and The Medicines Company). The US Food and Drug Administration approved Leqvio in December 2021 as an adjunct to diet and maximally tolerated statin therapy for adults with heterozygous familial hypercholesterolaemia or clinical atherosclerotic cardiovascular disease who require additional LDL-cholesterol lowering. The dosing schedule is the operational differentiator from the monoclonal antibody PCSK9 inhibitors: a 284 mg subcutaneous injection at day 0, again at month 3, then every 6 months. Two injections per year on maintenance. Reserved for you.

Why UAE patients need Leqvio via a named-patient pathway

The UAE carries a high prevalence of familial hypercholesterolaemia (consanguinity-driven heterozygous and a meaningful homozygous burden) and a high atherosclerotic cardiovascular disease burden across the adult population. The standard regional regimen is high-intensity statin therapy (atorvastatin or rosuvastatin) plus ezetimibe. For patients who do not reach LDL-cholesterol targets on this combination, the PCSK9-directed family of therapies (evolocumab, alirocumab, and inclisiran) adds the next step.

Evolocumab (Repatha, Amgen) and alirocumab (Praluent, Sanofi-Regeneron) are monoclonal antibodies, dosed every two weeks or every four weeks. They hold MoHAP registration regionally and are more widely stocked. Leqvio's siRNA mechanism and its twice-yearly

maintenance schedule is the clinical differentiator. The case for Leqvio specifically is built when the patient prefers the twice-yearly schedule for adherence, when the monoclonal antibody PCSK9 inhibitors have not been tolerated, or when the treating cardiologist wants the siRNA mechanism for a specific patient. Leqvio is not consistently held in UAE federal stock. The EDE named-patient pathway is the established route.

The EDE / MoHAP named-patient pathway applied to Leqvio

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit, administered through the Emirates Drug Establishment (EDE) at ede.gov.ae. The EDE took over 44 core services from MoHAP 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 the medicine is approved by a recognised reference authority such as the US FDA and a locally registered alternative is not suitable.

For Leqvio, the clinical justification packet is structured around the lipid-management state. The treating cardiologist or lipidologist documents the diagnosis (heterozygous familial hypercholesterolaemia with genetic or clinical criteria, or clinical atherosclerotic cardiovascular disease), the LDL-cholesterol trajectory on maximally tolerated statin plus ezetimibe, the most recent LDL-cholesterol value, the LDL-cholesterol target per the treating guideline (typically less than 55 mg/dL or less than 1.4 mmol/L for very-high-risk patients per ESC/EAS), and the rationale for siRNA-based PCSK9 suppression over the monoclonal antibody alternatives.

A complete EDE application for Leqvio typically includes the cardiologist or lipidologist's clinical justification letter, the treating physician's MoHAP, DHA, DoH, or Sharjah Health Authority licence verification, an anonymised patient identifier, full product details (Leqvio 284 mg/1.5 mL prefilled syringe for subcutaneous injection), the destination dispensing facility name with licence number and pharmacy in charge, and the patient informed consent. Approval timelines for routine cases are 5 to 15 business days.

Where Leqvio gets dispensed in the UAE

Leqvio is administered by subcutaneous injection in a clinical setting by a healthcare professional. It is not for patient self-administration. The dispensing site is therefore tied to a clinic visit at day 0, month 3, and every 6 months thereafter. The most natural dispensing sites are the cardiology and lipid clinics at Cleveland Clinic Abu Dhabi, the Heart Hospital at the Sheikh Khalifa Medical City, American Hospital Dubai, Mediclinic City Hospital, NMC Royal Hospital, and the dedicated lipid clinics in Dubai Healthcare City. The drug is stored at

room temperature (20 to 25 degrees Celsius) and does not require refrigeration in the unopened prefilled syringe, which simplifies logistics relative to refrigerated biologics.

Real cost picture for Leqvio in the UAE

The US wholesale acquisition cost for Leqvio is approximately USD 3,500 to 4,000 per 284 mg dose, with two doses given in the first 3 months (loading) and two doses given per year on maintenance (every 6 months). Annual drug acquisition cost on maintenance is therefore approximately USD 7,000 to 8,000, translating to approximately AED 26,000 to 30,000 at the 3.67 peg. The figure is the drug acquisition cost only.

All-in delivered cost stacks the drug acquisition, ambient international logistics (USD 400 to 700 per shipment), EDE handling and customs (USD 300 to 600 per case), the dispensing facility's injection administration fee, and the Reserve Meds concierge coordination fee. The twice-yearly schedule means the logistics burden is low relative to the every-two-week or every-four-week monoclonal antibody schedules. Insurance in the UAE handles lipid-lowering biologics case by case. Pre-authorisation is the norm. Thiqa, administered by Daman, has the broadest specialty coverage. We do not promise coverage.

Typical timeline for Leqvio in the UAE

The EDE permit processes in 5 to 15 business days for a routine submission with a clear lipid-management rationale and a documented statin-and-ezetimibe trail. International logistics for an ambient-shipped subcutaneous injection adds 3 to 7 business days. Customs clearance is typically 1 to 3 business days. A patient who completes the documentation in week one typically receives the first injection in week three to week five. The second loading dose is given at month 3 and maintenance thereafter is every 6 months.

What your physician needs to provide

The clinical justification letter for a Leqvio EDE submission is tightly scoped. The treating cardiologist or lipidologist's letter typically addresses the diagnosis (heterozygous familial hypercholesterolaemia or clinical atherosclerotic cardiovascular disease), the current statin regimen and dose at maximum tolerated, the ezetimibe history, the LDL-cholesterol trajectory and most recent value, the LDL-cholesterol target per the treating guideline, the prior PCSK9 monoclonal antibody experience where applicable, and the rationale for siRNA-based PCSK9 suppression. The letter references the Novartis US label and the dosing schedule (day 0, month 3, then every 6 months).

The treating physician's licence must be in active standing in the emirate of the dispensing facility (MoHAP for the Northern Emirates, DHA for Dubai, DoH for Abu Dhabi and Al Ain, Sharjah Health Authority for Sharjah). The patient signs informed consent for the named-

patient route. The dispensing facility's pharmacy in charge holds the establishment licence the EDE verifies.

Pharmacovigilance considerations

The adverse-event profile of Leqvio is dominated by injection-site reactions, which are typically mild and self-limited. The siRNA mechanism reduces PCSK9 synthesis durably, which supports the every-6-month dosing on maintenance. Pharmacovigilance follow-up is light relative to the chronic biologics: the cardiology team monitors LDL-cholesterol at baseline, at month 3 (before the second loading dose), at month 6 (before the first maintenance dose), and then at each maintenance visit. Adverse events identified by the treating team route to Novartis's safety reporting channel and to the EDE post-market surveillance address.

Common questions about Leqvio in the UAE

Why Leqvio rather than evolocumab (Repatha) or alirocumab (Praluent)? The three PCSK9-directed therapies achieve comparable LDL-cholesterol reductions in the relevant indications. The differentiation is dosing: evolocumab and alirocumab are monoclonal antibodies given every two weeks or every four weeks, typically as patient self-administered subcutaneous injections; Leqvio is an siRNA given by a healthcare professional twice yearly on maintenance. For patients who struggle with frequent self-injection or for whom the every-6-month adherence pattern is preferred, Leqvio is the differentiated option. The clinical choice rests with the treating cardiologist.

Will Daman, Thiqa, or my private insurer cover this? Each insurer assesses lipid-lowering biologics case by case. Pre-authorisation is the norm. Thiqa has the broadest specialty coverage. We do not promise coverage.

Is Leqvio a controlled substance? No. Leqvio is not a DEA scheduled substance.

Do I need to keep taking my statin? Yes. The US label position is that Leqvio is added as an adjunct to maximally tolerated statin therapy. The cardiologist defines the regimen.

What patients ask when they first call

"How does the case actually start?" The patient or the treating cardiologist or lipidologist contacts Reserve Meds through the waitlist form. Within 24 to 48 hours, a coordinator confirms eligibility, sends the documentation kit to the physician, and outlines the EDE submission sequence. No payment is taken at this stage.

"How do I know inclisiran is working?" LDL-cholesterol measurements at baseline, at month 3 (before the second loading dose), and at month 6 (before the first maintenance dose) document the response. The siRNA mechanism produces a durable LDL-cholesterol reduction that is sustained between maintenance doses. The treating cardiologist interprets the trend in the context of the cardiovascular risk picture.

"What if I miss the every-6-month maintenance dose by a few weeks?" The US label provides specific guidance on missed-dose management. Short delays (within a few weeks) are typically managed by giving the next dose at the next scheduled clinic visit. Longer delays may require restarting the loading sequence. The treating clinic team makes the call.

"Are there any drug-drug interactions I should worry about?" Inclisiran does not interact through the CYP450 enzyme system because it is an siRNA, not a small molecule. The interaction profile is therefore lighter than with statins or with the small-molecule lipid-lowering agents. The treating cardiologist reviews concurrent medication for completeness.

Where Reserve Meds fits in Leqvio cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating cardiologist or lipidologist, the EDE, or the dispensing pharmacy. For a Leqvio case, our work is the regulatory documentation assembly, the US-side procurement coordination with the Novartis specialty distributor, the logistics, the customs handoff, and a single named coordinator for the patient through the loading set and the recurring twice-yearly maintenance supply. The twice-yearly schedule means we hold a long, light cadence with the patient. Reserved for you.

Documentation kit for the treating cardiologist or lipidologist

The documentation kit Reserve Meds sends the treating cardiologist or lipidologist after a waitlist confirmation contains the EDE clinical-justification letter template tailored to the PCSK9-directed siRNA mechanism, the LDL-cholesterol trajectory capture sheet, the statin and ezetimibe outcome template, the prior PCSK9 monoclonal antibody capture sheet where applicable, the dosing schedule template (day 0, month 3, then every 6 months), the patient informed consent template, the dispensing clinic intake checklist for the twice-yearly cadence, the LDL-cholesterol monitoring schedule, and the long-cadence patient follow-up reminder. The kit is built so the cardiology or lipid clinic spends minimum time on form work and maximum time on the lipid-management conversation that anchors the regimen.

Next step

If a treating cardiologist or lipidologist in the UAE is weighing Leqvio for an adult patient, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Leqvio clinical resource
- Familial hypercholesterolaemia
- Atherosclerotic cardiovascular disease
- United Arab Emirates country page

Sources

1. FDA approval, Leqvio (inclisiran), Novartis, approval December 2021 for heterozygous familial hypercholesterolaemia or clinical ASCVD requiring additional LDL-cholesterol lowering.
2. UAE Federal Decree-Law No. 38 of 2024 and the Emirates Drug Establishment portal at ede.gov.ae.
3. Novartis US prescribing information for Leqvio (inclisiran), 284 mg/1.5 mL prefilled syringe; dosing at day 0, month 3, then every 6 months.