Leqvio

Saudi Arabia · access guide

How to access Leqvio from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Saudi Arabia patient with established atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolaemia, or statin-intolerance who is not at LDL-C goal on maximally tolerated statin (with or without ezetimibe) may receive a prescription for Leqvio (inclisiran) from their treating cardiologist or lipidologist. Leqvio is FDA-approved for LDL-C lowering in these populations and is developed by Novartis. Leqvio is available in some Saudi Arabia tertiary facilities, but formulary coverage is uneven; where your specific hospital formulary does not stock Leqvio or where the required dosing schedule is not coordinated in-house, the named-patient pathway is a legitimate bridge.

This guide explains how Reserve Meds supports access in that formulary-gap scenario and where we fit in.

The clinical situation

Leqvio is a small interfering RNA (siRNA) therapy targeting PCSK9 messenger RNA in hepatocytes, administered subcutaneously on a loading schedule (Day 0, Day 90) then every six months. Twice-yearly dosing is a meaningful adherence advantage versus weekly/biweekly PCSK9 monoclonal antibodies. Eligibility anchors to lipid panel history, ASCVD or HeFH documentation, and evidence of maximally tolerated statin therapy. Your cardiologist will confirm baseline LDL-C, set a follow-up lipid cadence, and document the clinical rationale.

Is Leqvio legally importable into Saudi Arabia?

Yes, via the Saudi Food and Drug Authority (SFDA) named-patient import framework (with DoH Abu Dhabi / DHA Dubai parallel authority) when Leqvio is not on your specific hospital formulary or when the specific dosing coordination is not locally available.

The named-patient mechanism permits a Saudi Arabia-licensed physician to import a medicine not routinely stocked at a given institution when (a) the medicine is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent alternative is available at that institution for the patient, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented. For a formulary-gap case, the rationale emphasises the specific institution's unavailability and the patient's clinical need.

How the pathway works, step by step

1. **Consultation with your treating cardiologist or lipidologist.** ASCVD / HeFH documentation, statin history, LDL-C trajectory, and clinical rationale.
2. **Baseline assessment.** Full lipid panel, hepatic and renal function, and monitoring-cadence plan.
3. **SFDA named-patient application.** The physician or hospital pharmacy files clinical rationale (including the formulary-gap note), patient reference, and dosing schedule.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Leqvio from authorised distribution under DSCSA.
5. **Cold-chain shipment.** Leqvio ships with temperature control to the prescribing hospital pharmacy.
6. **Arrival and administration.** The clinic administers the subcutaneous dose on the Day 0 / Day 90 / every-6-month cadence.

What documentation your physician needs

- Clinical rationale letter confirming indication (ASCVD / HeFH / statin-intolerance), maximally tolerated therapy history, and Leqvio as indicated therapy
- Verification of Saudi Arabia medical license
- Lipid-panel history documenting LDL-C above goal
- Institutional note confirming formulary gap (if applicable)
- Planned dosing schedule (Day 0, Day 90, then every 6 months) and follow-up LDL-C cadence

Reserve Meds provides a physician documentation kit bundling SFDA templates and the formulary-gap clinical-rationale language.

Costs and timing

Leqvio's US cash-pay drug-only reference cost sits in an indicative 2026 annual range of roughly USD 6,500-7,500 (two doses per year). International logistics, SFDA documentation handling, cold-chain shipment, and concierge coordination add incremental cost. Reserve Meds issues a transparent quote at the start of intake. Indicative range.

Indicative timing for first dose after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

Reserve Meds's role

- **Sourcing.** Through our US-licensed specialty wholesale partner under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and SFDA review, including the formulary-gap rationale.
- **Logistics.** Validated cold-chain shipment to your prescribing hospital.
- **Concierge case lead.** A named point of contact coordinating the semi-annual dosing cadence.

What we do not do: We are not the prescriber, do not practise medicine, and are not the dispensing pharmacy. All clinical decisions remain with your treating cardiologist.

Frequently asked

My hospital already stocks Leqvio, do I need this pathway? No, if your hospital routinely stocks and dispenses Leqvio for your indication, use the local pathway. Reserve Meds steps in only where there is a formulary or supply gap.

How often do I dose after the loading phase? Day 0, Day 90, then every six months, a total of two maintenance doses per year.

How does Leqvio compare with Praluent or Repatha? All three are PCSK9-pathway therapies. Leqvio (siRNA) is dosed twice yearly; Praluent and Repatha (monoclonal antibodies) are dosed every 2-4 weeks. Your cardiologist selects based on adherence profile and clinical picture.

Will insurance cover this? Cash-pay is the default for named-patient imports. Some Saudi Arabia private insurers consider case-by-case reimbursement; we supply documentation but do not process claims directly.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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