

Oxlumo

Saudi Arabia · access guide

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

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

A Saudi Arabia patient, paediatric or adult, diagnosed with primary hyperoxaluria type 1 (PH1) may receive a prescription for Oxlumo (lumasiran) from their treating nephrologist or metabolic-disease specialist. Oxlumo is FDA-approved for PH1 across all ages and is developed by Alnylam Pharmaceuticals. PH1 is ultra-rare, and routine stocking through Saudi Arabia hospital pharmacies is inconsistent, so access typically runs through the named-patient import pathway coordinated with the patient's tertiary care centre in Abu Dhabi, Dubai, or Sharjah.

This guide explains the legal pathway, the documentation your physician prepares, typical timing, indicative cost posture, and where Reserve Meds fits in.

The clinical situation

Oxlumo is a subcutaneous small interfering RNA (siRNA) therapy that reduces hepatic oxalate production at the source, by silencing the HAO1 gene encoding glycolate oxidase. In PH1, the underlying AGXT deficiency drives oxalate overproduction, recurrent kidney stones, nephrocalcinosis, and progressive chronic kidney disease that frequently advances to end-stage renal disease and the need for combined liver-kidney transplantation. Oxlumo is indicated specifically for PH1. Dosing is weight-based, with a loading phase (monthly for three doses) followed by maintenance, monthly for young children and quarterly for larger patients per label. Eligibility is anchored in biochemical and genetic confirmation of PH1 (elevated urinary oxalate, AGXT mutations) and specialist-led management. Your physician will establish baseline urinary oxalate, creatinine, eGFR, renal imaging, and a long-term follow-up cadence.

Is Oxlumo legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient import framework, with parallel authority operated by the Department of Health (DoH) in Abu Dhabi and the Dubai Health Authority (DHA) in Dubai depending on where the prescribing facility sits.

The named-patient mechanism permits a Saudi Arabia-licensed physician to import a medicine not locally registered when (a) it is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent locally available alternative suits the specific patient, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented end-to-end. PH1 has no clinically equivalent registered alternative on Saudi Arabia formularies, which supports clinical rationale.

How the pathway works, step by step

1. **Consultation with your treating nephrologist or metabolic-disease specialist.** AGXT genetic report, urinary oxalate measurements, and a clinical rationale letter.
2. **Baseline assessment.** 24-hour urinary oxalate (or spot oxalate:creatinine ratio for young children), eGFR, renal ultrasound, and plasma oxalate where relevant.
3. **SFDA named-patient application.** The physician or hospital pharmacy files clinical rationale, patient reference, weight-based dosing plan, and chain-of-custody commitment.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Oxlumo from authorised distribution under DSCSA.
5. **Cold-chain shipment.** Oxlumo requires refrigerated handling; shipment follows validated cold-chain protocols with temperature logging.
6. **Arrival and administration.** The hospital pharmacy releases the product; the paediatric or adult clinic administers the subcutaneous dose and schedules the next.

What documentation your physician needs

- Clinical rationale letter confirming PH1 and Oxlumo as the indicated therapy
- Verification of Saudi Arabia medical license
- AGXT genetic test result and biochemical workup (elevated urinary oxalate)
- Baseline eGFR, renal ultrasound, and plasma oxalate where relevant
- Patient weight (for weight-based dosing) and age
- Planned dosing schedule (loading + maintenance) and long-term monitoring plan

Reserve Meds provides a physician documentation kit bundling the templates SFDA reviewers expect for ultra-rare paediatric/adult metabolic disease named-patient imports.

Costs and timing

Oxlumo for PH1 is a substantial ultra-rare-disease therapy. Reference US cash-pay for a full annual course (weight-based, loading-plus-maintenance dosing) typically sits in the high six to seven-figure USD range depending on patient weight. Reserve Meds operates on a drug-only reference basis and provides a transparent, itemised delivered quote, covering product, cold-chain logistics, SFDA documentation handling, customs clearance, and concierge coordination, at the start of intake. Figures are indicative, not a binding quote until intake is complete.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted. Subsequent doses are scheduled according to the weight-based maintenance cadence.

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 / DoH / DHA review.
- **Logistics.** Validated cold-chain shipment to your prescribing hospital pharmacy.
- **Concierge case lead.** A named point of contact coordinating long-term refills for paediatric or adult PH1 cases.

What we do not do: We are not the prescriber. We do not practise medicine. We are not the dispensing pharmacy. All clinical decisions remain with your treating nephrologist or metabolic-disease specialist.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the SFDA / DoH / DHA named-patient framework with appropriate documentation. See our trust and compliance page.

How is Oxlumo different from Rivfloza? Both are siRNA therapies targeting oxalate overproduction in primary hyperoxaluria. Oxlumo is FDA-labeled specifically for PH1 across all ages. Rivfloza (nedosiran) has a different labelled population. Your specialist will select based on the genetic subtype, age, and clinical picture.

Does Oxlumo cure PH1? No disease-modifying therapy is curative in PH1, but Oxlumo substantially reduces urinary oxalate and can slow disease progression. Transplant considerations remain individualised.

Will insurance cover this? Cash-pay is the default. Some Saudi Arabia private insurers consider ultra-rare paediatric imports case by case; we supply documentation for your submission but do not process insurance 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.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

reservemeds.com · hello@reservemeds.com