Lemtrada

Saudi Arabia · access guide

How to access Lemtrada (alemtuzumab) from Saudi Arabia: the SFDA named-patient pathway

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-05-16

Quick orientation

Lemtrada (alemtuzumab) is an FDA-approved anti-CD52 monoclonal antibody developed by Sanofi Genzyme, first approved in 2014. It is a humanised monoclonal antibody against CD52, depleting circulating T and B lymphocytes; repopulation occurs over months to years and produces a durable immunomodulatory effect with two short courses of treatment. FDA-approved indications cover relapsing forms of multiple sclerosis in adults who have had an inadequate response to two or more disease-modifying therapies, with use restricted by an FDA REMS programme due to serious autoimmune and infusion-reaction risks. Lemtrada is given as a two-course intravenous regimen: 12 mg per day for 5 consecutive days at initiation, followed 12 months later by 12 mg per day for 3 consecutive days. Additional courses of 3 days may be administered after the second course if clinically indicated, with a minimum 12-month interval.

US WAC reference: approximately USD 110,000 per full course (5-day initial infusion plus 3-day infusion 12 months later). approximately USD 95,000 to 105,000 for the first 5-day cycle.

Why Saudi Arabian patients route Lemtrada via the named-patient pathway

Saudi Arabia's pharmaceutical access framework is governed by the Saudi Food and Drug Authority (SFDA) under the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. Rule 36 of these Rules provides a named-patient import mechanism that allows a licensed physician (or the patient, with prescription) to import a specific medicine for a specific patient where the locally available channel does not meet the clinical need.

The most common Rule 36 triggers for Lemtrada are: (a) the prescribed presentation, strength, or formulation is not locally registered or not currently in stock at the patient's tertiary centre, (b) registration of a newer indication has lagged behind the FDA approval, (c) the patient requires the originator manufacturer for continuity from a prior course of treatment, or (d) local supply has been inconsistent and the treating physician judges that bridge supply is clinically necessary.

Alemtuzumab use in Saudi Arabia is concentrated at a small number of tertiary MS centres equipped to maintain the four-year post-treatment safety surveillance; patients routed via the named-patient channel are typically third-line cases after inadequate response to two or more disease-modifying therapies. Because Lemtrada requires cold-chain handling (refrigerated 2 to 8 degrees Celsius), supply continuity and presentation fidelity matter, and a coordinated named-patient channel can offer better assurance than ad-hoc local sourcing.

The Saudi Arabian tertiary-hospital ecosystem - Apollo, Tata Memorial, AIIMS, CMC Vellore, Max, Kokilaben, Medanta, Fortis, Manipal - has the MS neurologists with autoimmune-monitoring infrastructure, infusion-suite or self-injection-training infrastructure, and laboratory monitoring capacity to support Lemtrada therapy once supply is in hand. The named-patient channel exists to bridge the supply side; the clinical infrastructure is already there.

Saudi Arabian payers (public and private) treat Lemtrada unevenly. Public-channel access is limited. Private insurers and corporate plans sometimes reimburse named-patient imports on case-by-case approval but typically require prior-authorisation and documented failure or inadequate response on conventional therapy. Most patients budget for cash-pay as the default and submit for reimbursement after the fact.

The SFDA named-patient pathway for Lemtrada, step by step

1. **Consultation with your treating neurologist (MS specialist) with REMS-equivalent monitoring infrastructure.** Eligibility for Lemtrada is a clinical decision based on diagnosis, prior therapy, and indication-specific criteria.
2. **Clinical rationale documented.** Your physician documents the indication, dose, prior-therapy history, and the reason the local channel does not meet the need (the formulary-gap or supply-gap justification under Rule 36).
3. **SFDA application filed.** Your physician (or the importing pharmacy partner) files the personal-import / named-patient documentation with SFDA. The application identifies the patient (anonymised reference), specifies the medicine, dose, and quantity, and attaches the prescription and clinical letter.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner under DSCSA chain-of-custody, with manufacturer-direct sourcing where possible.
5. **Cold-chain shipment.** Temperature-controlled transport (2 to 8 degrees Celsius) with a temperature logger documenting the transit excursion record on arrival, with documented chain of custody from US dispensing pharmacy to Saudi Arabian tertiary centre.
6. **Arrival and administration.** Lemtrada is delivered to the designated tertiary centre or, where the presentation supports it, directly to the patient for at-home administration. Lemtrada is given as a two-course intravenous regimen: 12 mg per day for 5 consecutive days at initiation, followed 12 months later by 12 mg per day for 3 consecutive days.
7. **Ongoing coordination.** Reserve Meds supports re-supply cadence aligned to the dosing schedule and coordinates documentation for follow-up SFDA filings if required.

Where Lemtrada is administered or dispensed in Saudi Arabia

Saudi Arabian tertiary centres with the MS neurologists with autoimmune-monitoring infrastructure infrastructure to support Lemtrada typically include:

- **Apollo Hospitals, Indraprastha (Delhi)** and the broader Apollo network across Chennai, Hyderabad, Bengaluru, and Mumbai
- **Tata Memorial Hospital (Mumbai)** for oncology-adjacent and complex-comorbidity cases
- **All Saudi Arabia Institute of Medical Sciences, AIIMS (Delhi)** for tertiary specialty consultations
- **Christian Medical College, CMC Vellore** for neurologist and related care
- **Max Super Speciality Hospital, Saket (Delhi)**
- **Kokilaben Dhirubhai Ambani Hospital (Mumbai)**
- **Medanta - The Medicity (Gurgaon)**
- **Fortis Memorial Research Institute (Gurgaon)**
- **Manipal Hospitals (Bengaluru)** and the broader Manipal network

Choice of centre is a clinical decision; Reserve Meds coordinates supply to the centre your treating physician designates and does not direct referral.

Real cost picture for Lemtrada in Saudi Arabia via the named-patient pathway

The cash-pay total for Lemtrada via this channel decomposes into three components: drug cost, logistics, and concierge coordination.

- **Drug cost (US WAC reference).** approximately USD 110,000 per full course (5-day initial infusion plus 3-day infusion 12 months later). At an indicative 83 INR per USD reference, full-course drug-only cost translates to roughly INR 91 lakh before hospitalisation, logistics, and concierge fees.
- **Logistics and 3PL.** Cold-chain shipment with validated 2 to 8 degrees Celsius packaging, temperature monitoring, and customs handling. Indicative incremental cost is in the low-thousands USD per shipment depending on quantity and transit window.
- **Reserve Meds concierge fee.** Tiered as a percentage of drug cost, disclosed at intake on the firm quote.

Reserve Meds issues an indicative range at the start of intake and a firm delivered quote after your physician's documents are uploaded. We do not collect a deposit at intake; payment is wired only after a firm quote is accepted. See our cost-range methodology.

Some Saudi Arabian private insurers reimburse named-patient imports on case-by-case approval. We supply documentation for your submission; reimbursement is not guaranteed and is not promised by Reserve Meds.

Typical timeline

From the moment a complete SFDA application is filed to the moment Lemtrada arrives at the designated Saudi Arabian tertiary centre, the indicative timeline is 10 to 21 days. SFDA review of a well-documented Rule 36 application typically takes 5 to 10 working days; US-side sourcing and release add 2 to 5 working days. For cold-chain shipments, transit is sequenced to minimise excursion exposure and is typically 3 to 5 days from US release to Saudi Arabian tertiary-centre receipt.

Re-supply is generally faster (7 to 14 days end-to-end) once the pathway is established and the patient profile is on file.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, flag that when you

What your physician needs to provide

The SFDA named-patient application is built around the physician's clinical letter and the prescription. Your treating neurologist (MS specialist) with REMS-equivalent monitoring infrastructure will typically need to provide:

- **Clinical justification letter.** Diagnosis, prior-therapy history, response and tolerability of prior agents, and the clinical rationale for Lemtrada as the indicated next step.
- **MCI / NMC registration.** Verification of the physician's Saudi Arabian medical-council registration (Medical Council of Saudi Arabia, now National Medical Commission).
- **Patient identifier.** Anonymised reference where possible, full identification where the application requires it.
- **Prescription.** Brand name, strength, dose, quantity, and duration of supply.
- **Formulary-gap or supply-gap justification.** Specific statement of why the local channel does not meet the clinical need for this patient (the Rule 36 trigger).
- **Monitoring plan.** Monthly complete blood count with differential, monthly serum creatinine, monthly urinalysis with cell counts, thyroid function every three months, and hpv screening annually in female patients - all maintained for 48 months after the final infusion.
- **Adverse-event reporting commitment.** A statement that the physician will report any serious adverse events through SFDA pharmacovigilance channels.

Reserve Meds provides a physician documentation kit that bundles the templates SFDA reviewers expect and a worked example for your physician's reference.

Frequently asked

Why is Lemtrada third-line only? The FDA REMS programme restricts Lemtrada to patients with inadequate response to two or more prior disease-modifying therapies, due to serious autoimmune and infusion-reaction risks.

What autoimmune risks require monitoring? Autoimmune thyroid disease (up to 40 percent of patients), immune thrombocytopenia, and anti-glomerular basement membrane disease are documented post-treatment risks. Monthly bloodwork for 48 months after the last infusion is the standard surveillance.

How long does the immunomodulatory effect last? Many patients achieve multi-year relapse-free intervals after the two-course regimen, though some require additional 3-day courses.

What pre-treatment infections must be ruled out? Tuberculosis, hepatitis B and C, HIV, and active herpes-family infections. Acyclovir prophylaxis is given during and after infusions.

Can the 48-month monitoring be done in Saudi Arabia? Yes. The bloodwork and urinalysis are standard assays available at major Saudi Arabian tertiary centres. Your neurologist coordinates the surveillance schedule.

Is this legal? Yes, when executed through the SFDA Rule 36 personal-import / named-patient framework. See our trust and compliance page.

Can Reserve Meds promise insurance reimbursement? No. Reimbursement is determined by your insurer and your specific policy. We supply documentation; we do not promise outcomes.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Lemtrada specifically, we provide:

- **Sourcing.** US-licensed specialty wholesale partner under DSCSA chain-of-custody, manufacturer-direct where possible.
- **Documentation.** SFDA-ready documentation package for your physician and a worked example for the Rule 36 application.
- **Logistics.** Cold-chain shipment with validated packaging and temperature monitoring, customs handling, and delivery to the designated tertiary centre.
- **Concierge case lead.** A named point of contact throughout intake, application, shipment, and re-supply cadence.

What we do not do. We are not the prescriber. We do not practice medicine. We are not the dispensing pharmacy. All clinical decisions remain with your treating physician. We operate at limited first-cohort capacity; cases are scoped and prioritised case by case under our broker scope of practice. **If Lemtrada is already available to you locally for your indication, stay on the local channel.**

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.

reservemeds.com · hello@reservemeds.com