Tepkinly

Saudi Arabia · access guide

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

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

A Saudi Arabia patient with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, or relapsed or refractory follicular lymphoma after two or more lines of systemic therapy may receive a prescription for Tepkinly (epcoritamab-bysp, marketed in the United States as Epkinly) from their treating hematologist. The product is FDA-approved and co-developed by AbbVie and Genmab. It is a CD3xCD20 T-cell engaging bispecific antibody administered by subcutaneous injection. Local availability of Tepkinly in the Saudi Arabia can be inconsistent: the drug may not be on every hospital pharmacy's standing hematology formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through SFDA remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

The clinical situation

Tepkinly is a humanised IgG1 bispecific antibody that simultaneously engages CD3 on T-cells and CD20 on malignant B-cells, redirecting cytotoxic T-cell activity to lymphoma cells. The regimen uses a step-up dosing schedule on cycle 1 to mitigate cytokine release syndrome (CRS), with full-dose subcutaneous injections continuing on a weekly, then every-other-week, then every-four-week cadence depending on cycle. Baseline workup per FDA labeling includes complete blood count with differential, hepatic function tests, hepatitis B serology, neurologic baseline assessment, and pregnancy testing where applicable. The FDA boxed warning covers cytokine release syndrome and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS). Step-up dosing typically requires hospital admission for the first full dose to monitor for CRS. Your hematologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Tepkinly legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. Parallel authority in the Emirate of Abu Dhabi operates through the Department of Health (DoH) and in Dubai through the Dubai Health Authority (DHA). The Saudi Arabia has an established pathway for specialty hematology medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The SFDA named-patient route allows a Saudi Arabia-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility. For bispecific antibodies with boxed warnings on CRS and ICANS, SFDA reviewers typically expect documentation of the admitting facility's CRS management protocol.

How the pathway works, step by step

1. **Consultation with your treating hematologist.** The prescribing decision is clinical. Your hematologist documents the indication, prior therapies (including any prior CAR-T or stem cell transplant), and rationale for Tepkinly.
2. **Baseline screening.** CBC, LFTs, hepatitis B serology, neurologic baseline, and pregnancy testing where applicable are confirmed and documented. The admitting facility's CRS management protocol is identified.
3. **SFDA named-patient application.** Your hematologist or the hospital's import pharmacy files the application with clinical rationale, patient reference, product strength, quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from AbbVie and Genmab's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Tepkinly requires refrigerated transport at 2 to 8 degrees Celsius. Shipments include temperature-monitored packaging with continuous loggers and tamper-evident seals.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your hematologist initiates therapy with step-up dosing in the inpatient setting.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis (DLBCL or follicular lymphoma subtype, prior lines, prior CAR-T or transplant status) and Tepkinly as the indicated next step
- Verification of their Saudi Arabia medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening (CBC, LFTs, hepatitis serology, neurologic baseline) consistent with FDA labeling
- The planned step-up dosing schedule and the admitting facility's CRS and ICANS management protocol
- A discussion note on the boxed-warning monitoring plan for cytokine release syndrome and neurologic toxicity

Reserve Meds provides a physician documentation kit that bundles the templates SFDA reviewers expect to see for CD3xCD20 bispecific antibodies, including the CRS and ICANS monitoring plan reviewers commonly request.

Typical costs and indicative timing

Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for the first cycle of Tepkinly (step-up doses plus first full dose) sits in an indicative 2026 band of roughly USD 38,000 to 52,000. Subsequent cycles run lower as dosing intervals lengthen. International logistics, SFDA documentation handling, cold-chain shipping, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 3 to 6 weeks from the moment a complete application is submitted to SFDA, assuming the documentation package is clean on first pass and the admitting facility CRS protocol is documented. Refills ship on a rolling cadence aligned to your dosing schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

Where Reserve Meds fits in

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

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for SFDA review, including bispecific-class CRS and ICANS monitoring templates.
- **Cold-chain logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility with continuous temperature loggers.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating hematologist, and dispensing sits with the licensed Saudi Arabia pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the SFDA (or DoH/DHA) named-patient framework with appropriate documentation, clinical rationale, and a licensed dispensing facility with a CRS-capable inpatient unit. The pathway is routinely used in Saudi Arabia hematology centers.

Is this the same drug as Epkinly? Yes. The active ingredient is epcoritamab-bysp. The brand name in the United States is Epkinly. The brand name in the European Union is Tepkinly. The product Reserve Meds sources is the FDA-approved Epkinly under DSCSA chain-of-custody from the US.

What about the boxed warning? The FDA boxed warning on epcoritamab covers cytokine release syndrome and neurologic toxicity (ICANS). The first full dose is typically administered with hospital admission for monitoring. Your hematologist performs the risk-benefit assessment and schedules CRS surveillance per labeling. Reserve Meds does not make that clinical judgement, your physician does.

Will my private health insurance cover this? Cash-pay is the default posture. Some Saudi Arabia private insurers reimburse named-patient hematology imports on a case-by-case basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

What if my hematologist has not filed a named-patient request before? Named-patient import is an institutional process most major Saudi Arabia hematology centers (Cleveland Clinic Abu Dhabi, American Hospital Dubai, Tawam Hospital, Mediclinic City Hospital) have encountered. Our documentation kit is written for first-time applicants and tracks what SFDA reviewers commonly ask for.

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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