

## Epkinly

Abu Dhabi · access guide

# How to access Epkinly from Abu Dhabi, the named-patient import pathway, 2026

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

A the UAEi 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 Epkinly (epcoritamab-bysp) from their treating hematologist. The product is FDA-approved in the United States and co-developed by AbbVie and Genmab (the brand name in the European Union is Tepkinly). It is a CD3xCD20 T-cell engaging bispecific antibody administered by subcutaneous injection. Local availability of Epkinly in Abu Dhabi 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 the Ministry of Public Health (MoPH) 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

Epkinly 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. Your hematologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

## Is Epkinly legally importable into the Abu Dhabi?

Yes, through the Ministry of Public Health (MoPH) of Abu Dhabi named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Abu Dhabi 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 MoPH named-patient route allows a the Abu Dhabi-licensed (under DoH) 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, MoPH reviewers typically expect documentation of the admitting facility's CRS management protocol.

## How the pathway works, step by step

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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 Epkinly.
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. **MoPH 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.** Epkinly 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

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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 Epkinly as the indicated next step
- Verification of their the DoH medical licence (Abu Dhabi emirate) (Abu Dhabi Council for Healthcare Practitioners registration)
- 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 MoPH reviewers expect to see for CD3xCD20 bispecific antibodies, including the CRS and ICANS monitoring plan reviewers commonly request.

## Typical costs and indicative timing

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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 Epkinly (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, MoPH 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 MoPH, 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.

## How an Abu Dhabi DLBCL case for Epkinly usually unfolds

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Most Epkinly cases out of Abu Dhabi originate at Cleveland Clinic Abu Dhabi haematology or Tawam Hospital oncology after CAR-T is not operationally feasible (no local apheresis-to-manufacturing chain that respects the DLBCL turnaround window) and after second-line or later chemoimmunotherapy has failed. Treating haematologists frequently weigh Epkinly against Columvi (glofitamab, also bispecific) and Polivy-R-CHP front-line if eligibility shifts.

The step-up dosing schedule on cycle 1 is the operational gate that drives admission planning. Most Abu Dhabi private hospitals will admit for the first three step-up doses with CRS monitoring, but the full-dose subcutaneous injections from cycle 1 day 22 onward usually move to oncology day-hospital. We confirm the admitting center has tocilizumab on hand and a standing CRS-management protocol before any case is greenlit.

The DoH named-patient committee asks for explicit prior-line documentation including response duration, biopsy confirmation of DLBCL transformation or refractoriness, and a CD20-positive flow cytometry report. We have found that pre-packaging the biopsy IHC alongside the clinical narrative cuts review time roughly in half versus serial submission.

Insurance behaviour: Daman platinum has reimbursed Epkinly twice on escalation review; most other plans decline at first pass, and the family typically self-funds the first two cycles while reimbursement appeals proceed. Typical end-to-end: four to six weeks if biopsy and prior-line records are already digital, longer if any record is paper-only.

### More questions, specific to this case

#### Is the CRS risk manageable outside a US-style cancer center?

Yes when the admitting center has tocilizumab on hand and a standing CRS-management protocol. Cleveland Clinic Abu Dhabi and SSMC both qualify. We confirm before any case is greenlit.

#### Why is Epkinly preferred over Columvi for some Abu Dhabi cases?

It is clinician preference. Subcutaneous administration after step-up is often cited as easier for outpatient continuation when the patient does not live within ICU-distance of the center. Both drugs are routinely considered.

**Can the patient receive Epkinly under their existing Abu Dhabi oncologist?**

Yes. Their existing oncologist continues to direct care. The admission for step-up dosing happens at a hospital with CRS-management capability and tocilizumab on standing order, your oncologist will name the partnering center on the MoPH submission.

***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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**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.

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