Columvi

Oman · access guide

How to access Columvi from Oman, the named-patient import pathway, 2026

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

A Oman patient with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy, may receive a prescription for Columvi (glofitamab-gxbm) from their treating hematologist. Columvi is FDA-approved in the United States and manufactured by Genentech, a member of the Roche Group. It is a CD20xCD3 T-cell engaging bispecific antibody administered as a fixed-duration intravenous regimen with step-up dosing. Local availability of Columvi in the Kingdom of Oman 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 Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) 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

Columvi is a humanised IgG1 bispecific antibody with a 2:1 CD20:CD3 binding configuration. The regimen is fixed-duration, typically up to 12 cycles, with step-up dosing in cycle 1 (2.5 mg, then 10 mg) before the first full target dose of 30 mg to mitigate cytokine release syndrome. Pretreatment with obinutuzumab is given seven days before the first Columvi dose to deplete circulating B-cells. 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 (CRS) which can be serious or life-threatening. Step-up dosing typically requires hospital admission for monitoring during cycle 1. Your hematologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Columvi legally importable into Oman?

Yes, through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Kingdom 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 DGPADC named-patient route allows a Oman-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 a CRS boxed warning, DGPADC 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 autologous transplant), and rationale for Columvi.
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. **DGPADC named-patient application.** Your hematologist or the hospital's import pharmacy files the application with clinical rationale, patient reference, product strength, fixed-duration cycle plan (typically up to 12 cycles), and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from Genentech's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Columvi 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 obinutuzumab pretreatment and 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 not otherwise specified, or transformed large B-cell lymphoma), prior lines of therapy, and Columvi as the indicated next step
- Verification of their Oman medical licence (SCFHS 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 obinutuzumab pretreatment and step-up dosing schedule
- A discussion note on the boxed-warning monitoring plan for cytokine release syndrome

Reserve Meds provides a physician documentation kit that bundles the templates DGPADC reviewers expect to see for CD20xCD3 bispecific antibodies, including the CRS 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 a single Columvi cycle sits in an indicative 2026 band of roughly USD 16,000 to 22,000, with cycle 1 (including step-up doses) running higher. The full fixed-duration course of up to 12 cycles is a multi-month financial commitment. International logistics, DGPADC 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 DGPADC, 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 three-week cycle 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 Columvi 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 DGPADC review, including bispecific-class CRS 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 Oman pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility with a CRS-capable inpatient unit. The pathway is routinely used in Oman hematology centers.

What about the boxed warning? The FDA boxed warning on Columvi covers cytokine release syndrome, which can be serious or life-threatening. Hospital admission for cycle 1 step-up dosing is the standard practice. Your hematologist performs the risk-benefit assessment and schedules CRS surveillance per labeling. Reserve Meds does not make that clinical judgement, your physician does.

How does Columvi compare with CAR-T as a treatment option? Columvi is an off-the-shelf bispecific antibody with a fixed-duration regimen, whereas CAR-T (Yescarta, Breyanzi, Kymriah) requires patient cell collection and manufacturing. Both are options in the r/r DLBCL setting; the choice depends on prior therapy, fitness, and access. Your hematologist makes that determination.

Will my private health insurance cover this? Cash-pay is the default posture. Some Oman private insurers and CCHI-aligned plans 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 Oman hematology centers (King Faisal Specialist Hospital and Research Centre, King Abdulaziz Medical City, Princess Noorah Oncology Center) have encountered. Our documentation kit is written for first-time applicants and tracks what DGPADC 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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