

Breyanzi

Oman · access guide

How to access Breyanzi from Oman, the cross-border CAR-T pathway, 2026

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

A Oman patient with relapsed or refractory large B-cell lymphoma (LBCL) in the second-line or later setting, including diffuse large B-cell lymphoma not otherwise specified, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, or with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) after a BTK inhibitor and a BCL-2 inhibitor, or with relapsed or refractory mantle cell lymphoma, marginal zone lymphoma, or follicular lymphoma after two or more prior lines, may receive a recommendation for Breyanzi (lisocabtagene maraleucel) from their treating hematologist. Breyanzi is FDA-approved in the United States and manufactured by Bristol Myers Squibb. It is important to be clear up front: Breyanzi is an autologous anti-CD19 CAR T-cell therapy with a defined CD4:CD8 composition. It is not a ready-to-ship medicine. It is manufactured from the patient's own T-cells, which must be collected at a Breyanzi-certified treatment center and engineered at the BMS manufacturing facility before being returned for infusion. That makes the cross-border pathway materially different from a conventional named-patient drug import through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC).

This guide explains how the pathway actually works, what documentation your hematologist needs, indicative cost and timing, and where Reserve Meds fits in.

The clinical situation

Breyanzi is an autologous CD19-directed CAR T-cell product engineered with a defined 1:1 CD4:CD8 composition designed for a more predictable toxicity profile. The treatment course involves: leukapheresis at a Breyanzi-certified center to collect autologous T-cells; cryopreservation and shipment to the BMS manufacturing facility; CAR-T cell engineering and expansion over approximately 3 to 4 weeks; return shipment of the patient-specific product; lymphodepleting chemotherapy (typically fludarabine and cyclophosphamide) in the days before infusion; infusion of the CAR T-cell product; and inpatient monitoring with discharge criteria typically requiring the patient to remain within 2 hours of the treatment center for 4 weeks post-infusion. The FDA boxed warning covers cytokine release syndrome (CRS) and neurologic toxicities, both of which can be severe or life-threatening. Breyanzi is dispensed only under the Breyanzi REMS program in the US. Your hematologist will discuss the risk-benefit profile, the requirement for a certified center, and the practical logistics before initiating therapy.

How does this work across borders?

Because Breyanzi is an autologous cell therapy that requires a Breyanzi-certified center for both the leukapheresis collection and the infusion, the standard cross-border access pathway is patient travel to a US Breyanzi-certified center, not import of a drug into the Kingdom of Oman. The DGPADC named-patient framework supports import of medicines, but CAR-T cellular products are practically delivered via patient travel to a certified treatment facility under that facility's REMS-compliant protocol.

Reserve Meds can help coordinate the referral arc to a US Breyanzi-certified center, help your hematologist assemble the referral package, and coordinate the family logistics around the multi-week stay. We do not perform the leukapheresis, we do not manufacture the product, and we do not provide the infusion. Those are functions of the US treatment center under its FDA REMS authorisation.

How the pathway works, step by step

1. **Consultation with your treating hematologist in Oman.** The recommendation for CAR-T is clinical, based on relapse pattern, prior lines (including any prior CAR-T or transplant), and fitness for the regimen. Your hematologist documents this rationale.
2. **Referral package to a US Breyanzi-certified center.** Pathology, imaging, prior-therapy summary, performance status, organ function panel, and infectious disease screening are assembled into a referral package.
3. **US center evaluation.** The US center reviews the package, accepts the referral (or asks for additional workup), and schedules the leukapheresis collection.
4. **Patient travel and leukapheresis.** The patient travels to the US center for collection. Reserve Meds coordinates travel, accommodations, and a designated caregiver presence requirement.
5. **Manufacturing.** The collected cells ship to the BMS manufacturing facility. Engineering and quality release take approximately 3 to 4 weeks.
6. **Lymphodepletion and infusion.** The patient receives lymphodepleting chemotherapy, then the CAR T-cell infusion at the certified center, with monitoring for CRS and neurologic toxicity.
7. **Post-infusion monitoring.** The patient remains within 2 hours of the treatment center for approximately 4 weeks post-infusion, then transitions to ongoing follow-up coordinated between the US center and Oman hematologist.

What documentation your hematologist needs

Your hematologist will typically need to assemble:

- A clinical summary letter confirming diagnosis (LBCL, CLL/SLL, MCL, MZL, or FL subtype, prior lines, prior CAR-T or transplant status), relapse pattern, and Breyanzi as the recommended next step
- Pathology reports including CD19 expression status
- Imaging (PET/CT preferred) within recent timeframe
- Organ function panel (CBC, CMP, LDH, LFTs), echocardiogram, pulmonary function tests
- Infectious disease screening (HIV, HBV, HCV, CMV serologies)
- Performance status documentation
- Confirmation that the patient has a designated caregiver who can accompany them for the duration of US treatment

Reserve Meds provides a CAR-T referral kit that bundles what US Breyanzi-certified centers expect to see in a complete referral package.

Typical costs and indicative timing

Reserve Meds gives you a transparent reference range and an itemised quote at intake. As an illustrative composite case, the US cash-pay reference range for the Breyanzi product itself sits in an indicative 2026 band of roughly USD 480,000 to 535,000. The treatment center facility and physician fees, lymphodepletion, inpatient monitoring, complication management, and post-infusion follow-up add substantially more, often bringing the total course cost to USD 700,000 to 1,000,000 or higher. Travel, accommodations, caregiver presence, and the multi-week stay are additional. Reserve Meds itemises each component in the delivered quote at intake.

Indicative timing from referral acceptance to infusion is typically 5 to 9 weeks: 1 to 2 weeks to schedule and complete the patient travel and leukapheresis, 3 to 4 weeks for manufacturing, and 1 week for lymphodepletion and infusion. The post-infusion stay in the US is approximately 4 additional weeks.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees. CAR-T cases require additional vetting given the clinical complexity and cost profile.

Where Reserve Meds fits in

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

- **Referral coordination.** We work with your Oman hematologist to identify candidate Breyanzi-certified centers and route the referral package.
- **Documentation.** Referral package assembly aligned with US center intake requirements.
- **Travel and logistics.** Coordination of patient and caregiver travel, accommodation near the treatment center, and the multi-week stay.
- **Concierge case lead.** A named point of contact for the family across the full case arc.

Reserve Meds coordination fee for this pathway.

A flat concierge fee of **USD 15,000 to 35,000** per case, scaled to the complexity of the pre-trip, in-US, and post-trip coordination required. The fee covers candidate US-certified center selection, referral package assembly and routing, pre-trip clinical workup and records transmission, financial-clearance coordination with the receiving center, visa and travel logistics for the patient and caregiver, in-US transport and translator support where needed, and post-trip clinical follow-up coordination back to the treating hematologist for 6 to 12 months.

The fee is paid directly to Reserve Meds. The CAR-T product cost, the US treatment-center charges, and any third-party travel and accommodation expenses are paid by the patient or family directly to the relevant counterparty. Reserve Meds does not mark up the center or the manufacturer, and Reserve Meds does not receive a referral fee from the center for the first patient cohort.

An itemised quote is issued at intake. Cash-pay only. No insurance billed.

We are a coordinator. We are not the prescriber, not a US treatment center, not the manufacturer of the cellular product, and not an oncology provider. The US treatment center is the clinical entity providing CAR-T under its FDA REMS authorisation. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal? Yes. Patient travel to a US-certified CAR-T center is a long-established pathway used by international patients. Reserve Meds operates as the coordination layer, not the clinical provider.

How does Breyanzi compare with Yescarta? Both are CD19-directed autologous CAR-T products. Breyanzi has a defined CD4:CD8 cell composition designed for a more controlled toxicity profile and a broader range of FDA-approved indications including CLL/SLL after BTKi and BCL-2 inhibitor failure. Yescarta has more years of follow-up data in LBCL. Your hematologist makes that determination based on disease, fitness, and prior therapy.

Can I get CAR-T in Oman instead? CAR-T capability is available at major Oman tertiary centers (King Faisal Specialist Hospital and Research Centre has an established CAR-T program). If your hematologist concludes a local certified CAR-T option is appropriate, that is typically the simpler pathway. Reserve Meds is most useful when the local option is not available or your case requires a US specialist evaluation.

What about the boxed warning for CRS and neurotoxicity? Cytokine release syndrome and neurotoxicity are managed by the certified treatment center under its REMS-compliant protocol with inpatient monitoring, tocilizumab and steroid availability, and ICU access. Your hematologist and the US treatment team perform that clinical management. Reserve Meds does not.

Will my private health insurance cover this? Cash-pay is the default posture. Some Oman private insurers and CCHI-aligned plans review CAR-T case-by-case on a pre-authorisation basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

What if I cannot travel to the US? Then cross-border Breyanzi access is not feasible via this pathway, and your hematologist should explore locally available CAR-T programs, bispecific antibody alternatives (Columvi, Epkinly), or other regimens. Reserve Meds will tell you that directly rather than charge for a service that cannot deliver.

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