Breyanzi

Saudi Arabia · access guide

How to access Breyanzi for relapsed or refractory large B-cell lymphoma, CLL, mantle cell lymphoma, or follicular lymphoma from Saudi Arabia: 2026 pathway via KFSHRC, KAMC, KFMC and the wider kingdom haematology network

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Saudi Arabia has the deepest adult CAR-T programme in the Gulf. King Faisal Specialist Hospital and Research Centre in Riyadh has treated more than 200 commercial CAR-T patients since 2020, and in late 2025 KFSHRC opened an in-house point-of-care anti-CD19 CAR-T manufacturing facility that has demonstrated approximately 80 percent cost reduction versus commercial CAR-T for academic CD19 products. King Abdulaziz Medical City under National Guard Health Affairs, King Fahad Medical City in Riyadh, and KFSHRC Jeddah complete the kingdom haematology network for B-cell lymphoma and CLL referrals. Breyanzi is registered with the SFDA, and the operational question for a Saudi patient with relapsed or refractory large B-cell lymphoma, CLL after BTK and venetoclax, mantle cell lymphoma after BTK, or follicular lymphoma after two or more lines is which kingdom centre fits the case and what the full pathway looks like once apheresis, manufacturing wait, bridging therapy, infusion and the post-infusion REMS-restricted month are added together.

This page explains how the pathway works in 2026 for a Saudi-resident adult: who qualifies, where the workup happens, where the cells are collected and infused, what the timeline looks like, what the realistic cost band is in SAR, and what to expect from the four-week REMS-restricted period after infusion. It is concierge documentation written for a family that is already in conversation with a treating haematologist and wants the operational reality laid out plainly.

Why Breyanzi, and why now

Breyanzi is lisocabtagene maraleucel, a one-time autologous CD19-directed CAR T-cell therapy with a defined 1:1 CD4:CD8 ratio. It reached the US market in February 2021 for third-line and later LBCL, expanded to second-line LBCL in June 2022 based on the TRANSFORM Phase 3 trial, then to CLL and follicular lymphoma in March 2024 and to mantle cell lymphoma in May 2024. Breyanzi is the only CD19 CAR-T currently labelled across all five indications.

For a Saudi patient with LBCL who has progressed on R-CHOP induction, TRANSFORM showed event-free survival of 10.1 months on Breyanzi versus 2.3 months on standard second-line therapy (chemoimmunotherapy plus autologous stem-cell transplant). For a CLL patient who has progressed on a BTK inhibitor and venetoclax, Breyanzi is the first CAR-T to receive an FDA label in CLL. For mantle cell lymphoma after BTK failure, Breyanzi and Tecartus are the two licensed CAR-Ts; KFSHRC has experience with both. For follicular lymphoma after two or more lines, the TRANSCEND FL trial reported an overall response rate of 95 percent.

The operational pathway is the same across indications: apheresis, approximately 24 days of manufacturing wait at the BMS facility (or in-house at KFSHRC for the academic CD19 product programme, which is a separate operational track from commercial Breyanzi), bridging therapy during the wait, lymphodepletion with fludarabine plus cyclophosphamide, single infusion, and the four-week REMS-restricted post-infusion period. This page focuses on the commercial Breyanzi pathway; the in-house academic CAR-T programme at KFSHRC is a parallel track for eligible patients enrolled into KFSHRC-led protocols.

What Breyanzi is, in plain language

A small volume of the patient's own blood is collected by apheresis. The T cells from that collection are sent to BMS's manufacturing facility, where they are separated into CD4 and CD8 fractions, each transduced with a lentiviral vector that teaches them to recognise CD19, a protein expressed on B cells and on the malignant B cells of LBCL, CLL, MCL, and follicular lymphoma. The two fractions are expanded separately and then combined in a defined 1:1 CD4:CD8 ratio. This ratio formulation is what distinguishes Breyanzi from the other CD19 CAR-T products and contributes to its favourable CRS profile in cross-trial comparison.

Manufacturing takes approximately 24 days. During manufacturing the patient continues bridging therapy where the disease tempo warrants, particularly in LBCL. When the product is ready, the patient receives three days of fludarabine plus cyclophosphamide lymphodepletion, then a single intravenous infusion of the manufactured Breyanzi at a target dose of 90 to 110 million CAR-positive viable T cells. Inpatient monitoring for cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome typically runs around seven days at KFSHRC and the other kingdom centres. The patient and a caregiver then stay within two hours of the treating centre for four weeks for REMS-mandated monitoring.

This is not a chronic medication. It is a one-time cell therapy, and the operational complexity sits in the apheresis, the manufacturing wait, the lymphodepletion, and the post-infusion month.

Eligibility at a kingdom haematologist's clinic

For Saudi-resident patients, the certified haematology programmes at KFSHRC, KAMC, KFMC, and KFSH Jeddah apply the FDA and EMA criteria with local adaptation. The eligibility floor varies by indication:

- LBCL: relapsed or refractory after one or more prior lines of systemic therapy. - CLL or SLL: relapsed or refractory after a BTK inhibitor and venetoclax. - Mantle cell lymphoma: relapsed or refractory after two or more prior lines including a BTK inhibitor. - Follicular lymphoma: relapsed or refractory after two or more prior lines.

Across all indications:

1. Histological confirmation of B-cell lymphoid malignancy by flow cytometry and immunohistochemistry; CD19 expression documented. 2. ECOG performance status 0 to 1; ECOG 2 reviewed case by case. 3. Adequate left ventricular ejection fraction, typically 45 percent or greater. 4. Adequate pulmonary function consistent with tolerating fludarabine-cyclophosphamide and a potential CRS event. 5. Adequate hepatic, renal, and bone marrow reserve. 6. No active central nervous system involvement of lymphoma in most contexts. 7. No active infection requiring systemic therapy. 8. A bridging therapy plan agreed with the treating haematologist for the manufacturing window where disease tempo warrants. 9. A caregiver commitment for the four-week REMS-restricted period.

A Saudi patient should arrive at the cell therapy referral conversation with the most recent diagnostic workup in hand: histopathology with immunohistochemistry and flow cytometry confirming the B-cell malignancy and CD19 expression, current PET-CT or CT staging, lactate dehydrogenase, complete blood count, comprehensive metabolic panel, echocardiogram, pulmonary function tests, hepatitis B and C and HIV serology, CMV status, and a current treatment history. Reserve Meds organises this documentation pack so the certified centre can give a yes or no eligibility opinion on the first review, not the fifth.

The kingdom administration picture, plainly

KFSHRC Riyadh runs the deepest adult CAR-T programme in the Gulf and is the reference centre for commercial CD19 CAR-T administration in the kingdom. KFSHRC has treated more than 200 commercial CAR-T patients since 2020 across CD19 and BCMA products. The in-house point-of-care anti-CD19 CAR-T manufacturing facility opened late 2025 is a separate operational track from commercial Breyanzi and serves patients enrolled into KFSHRC-led academic CD19 CAR-T protocols, with approximately 80 percent cost reduction versus commercial pricing. For commercial Breyanzi administration the standard pathway applies.

KFSHRC Jeddah is the secondary KSA cell therapy site, with the same SFDA registration and similar pathway design.

King Abdulaziz Medical City (Riyadh and Jeddah) under National Guard Health Affairs runs adult haematology and BMT programmes that take CD19 CAR-T referrals. King Fahad Medical City in Riyadh runs an adult haematology and lymphoma referral capacity.

For Saudi-resident adults where slot availability or geographic logistics warrant, cross-border alternatives include Cleveland Clinic Abu Dhabi and Sheikh Shakhbout Medical City in the UAE (adult cellular therapy programmes), King Hussein Cancer Center in Amman (the largest dedicated cancer centre in MENA with adult cell therapy accreditation), and select European or US centres.

The 2026 pathway, step by step

Week 0 to 2: Reserve Meds builds the document pack with the treating haematologist's office. We collect histopathology, imaging, treatment history, and laboratory panels. We submit a first-review request to KFSHRC or to one of the alternative kingdom centres.

Week 2 to 4: The certified centre's cell therapy committee reviews the case. If accepted, the centre opens a manufacturing slot with BMS and schedules apheresis. The financial pre-authorisation conversation starts in parallel.

Week 4 to 5: Apheresis at the certified centre. One to two sessions, outpatient.

Week 5 to 8: Manufacturing wait of approximately 24 days at the BMS facility. Bridging therapy during this window per treating haematologist's plan where disease tempo warrants.

Week 8: Lymphodepletion. Three days of fludarabine plus cyclophosphamide.

Week 8 to 9: Single inpatient Breyanzi infusion. Day 0 of the cell therapy clock.

Week 9 to 10: Inpatient monitoring for CRS and ICANS. Tocilizumab and corticosteroids per protocol. Median CRS onset around day five; median ICANS onset around day eight.

Week 10 to 13: REMS-restricted four-week post-infusion period. Patient and caregiver stay within two hours of the treating centre. No driving for 30 days. Twice-weekly clinic visits typically.

Month 4 onwards: Outpatient follow-up. Monthly disease assessment for the first year; then quarterly. Long-term haematology surveillance for cytopenias, infections, hypogammaglobulinaemia (often months to years requiring IVIG support), and second-primary malignancies including the class-wide T-cell malignancy signal per the FDA July 2024 boxed warning.

Cost expectation in SAR

US list price for the Breyanzi product itself is USD 419,500, set at parity with the other CD19 CAR-Ts. Real-world total cost of care including apheresis, bridging therapy, lymphodepletion, inpatient infusion and monitoring, CRS or ICANS management, and one-year follow-up commonly runs USD 700,000 to USD 1.2 million. At 2026 indicative cross rates the SAR-equivalent product price is approximately SAR 1.57 million and the total cost of care band is approximately SAR 2.6 to 4.5 million. Outliers run higher when prolonged ICU support or sustained cytopenias drive admission length.

For Saudi national patients on MoH or CCHI coverage, much of this cost may be underwritten by the public sector through the certified-centre referral pathway. KFSHRC, KAMC, KFMC, and KFSH Jeddah operate under MoH and National Guard Health Affairs funding arrangements that have historically extended to commercial CAR-T administration on indication-confirmed cases. For expatriate residents and self-pay families, the standard cash-pay-with-documentation pattern applies.

Monitoring through the first year

The first three months after infusion are the highest-acuity period. Cytopenias are common. Infection prophylaxis is standard. IVIG replacement for hypogammaglobulinaemia is often required and may continue for months to years.

Disease assessment by PET-CT, CT, or disease-specific markers proceeds monthly through year one and then quarterly. Long-term surveillance for second primary malignancies extends 15 years per REMS.

Religious, ethical, and family-logistics framing

The Islamic jurisprudence consensus on cell-based therapy for life-threatening illness is broadly permissive in the kingdom. Breyanzi is the patient's own T cells engineered ex vivo and re-infused; there is no donor element. Classical analogies to blood transfusion and organ transplant extend without difficulty.

The four-week REMS-restricted post-infusion period is the practical pressure point. For Saudi patients treated at KFSHRC Riyadh, families based outside Riyadh organise serviced accommodation for the month near the hospital. A caregiver must be present continuously. Reserve Meds documents the proximity-accommodation, transport, and pharmacy logistics in advance.

When Breyanzi is not the right call

For a Saudi patient where disease tempo is too rapid to accommodate the approximately 24-day manufacturing wait, where performance status has degraded below ECOG 2, where active CNS involvement has emerged, or where caregiver availability for the post-infusion month cannot be arranged, the operational alternative depends on the indication. For LBCL, a bispecific T-cell engager such as epcoritamab or glofitamab is off-the-shelf. For CLL, continued targeted-therapy salvage may be appropriate. For MCL, Tecartus is the alternative CD19 CAR-T with a different toxicity profile. For follicular lymphoma, mosunetuzumab is the bispecific alternative.

Reserve Meds does not promote one CD19 CAR-T over another. Across CD19 CAR-T products (Breyanzi, Yescarta, Kymriah, Tecartus) the choice is centre-specific, indication-specific, and toxicity-profile-specific; the page above describes the Breyanzi pathway because Breyanzi is the CAR-T the patient has asked about.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Saudi Breyanzi case we build the document pack, submit first-review requests to KFSHRC or to an alternative kingdom centre, run the financial pre-authorisation conversation alongside the clinical pre-authorisation conversation, coordinate the bridging-therapy logistics during the manufacturing window, organise the proximity accommodation and caregiver logistics for the four-week REMS-restricted period, and stay with the case through one-year follow-up. Clinical decisions remain with your treating haematologist and the certified cell therapy programme.

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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