Breyanzi

United Arab Emirates · access guide

How to access Breyanzi for relapsed or refractory large B-cell lymphoma, CLL, mantle cell lymphoma, or follicular lymphoma from the UAE: 2026 pathway via UAE certified cell therapy centres

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

The UAE has built one of the deepest adult cell therapy and bone marrow transplant infrastructures in the wider region. Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, Burjeel Medical City, Abu Dhabi Stem Cells Centre, and Yas Clinic Hospital all run adult haematology and cellular therapy programmes that handle B-cell lymphoma and CLL from diagnosis through later-line salvage. Breyanzi is registered with the Emirates Drug Establishment, and authorised cell therapy administration capability is evolving across this network in coordination with Bristol Myers Squibb's global Cell Therapy 360 programme. For a UAE 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, the operational question is no longer whether CD19-directed CAR-T is reachable: it is which certified centre fits the case, which cross-border path is the backstop, and what the total cost of care looks like once apheresis, manufacturing wait, bridging therapy, inpatient infusion and the post-infusion REMS-restricted month are added together.

This page explains how the pathway works in 2026 for a UAE-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, 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 developed by Juno Therapeutics and now marketed by Bristol Myers Squibb. It reached the US market in February 2021 for third-line and later LBCL, expanded to second-line LBCL in June 2022, 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 UAE patient who has progressed on R-CHOP induction and is being considered for second-line therapy in LBCL, the question of whether to pursue CD19 CAR-T versus salvage chemoimmunotherapy plus autologous stem-cell transplant is now a real clinical decision shaped by the TRANSFORM Phase 3 randomised trial, which showed event-free survival of 10.1 months on Breyanzi versus 2.3 months on standard second-line therapy. 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 and represents an alternative to continued targeted-therapy salvage or to one of the bispecific antibodies. For mantle cell lymphoma after BTK failure, Breyanzi and Tecartus are the two licensed CAR-Ts; the choice is centre-specific and toxicity-profile-specific. For follicular lymphoma after two or more lines, the TRANSCEND FL data showed an overall response rate of 95 percent and a complete response rate of 73 percent.

Across these indications the operational shape is the same: apheresis, approximately 24 days of manufacturing wait, bridging therapy during the wait, lymphodepletion, single infusion, and the four-week REMS-restricted post-infusion period. The clinical team weighs disease tempo, performance status, prior therapy exposure, and family logistics. This page is the operational layer underneath that conversation.

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 to therapeutic dose 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 to control disease burden, particularly in LBCL where disease tempo can be rapid. When the product is ready, the patient receives three days of fludarabine plus cyclophosphamide lymphodepletion to make room for the CAR-T cells to expand in vivo, 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 MENA 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. Most of the chronic-care infrastructure that a lymphoma or CLL patient is already familiar with (monthly clinic visits, infusion days, laboratory monitoring) collapses into a concentrated three-month operational window built around the infusion.

Eligibility at a UAE haematologist's clinic

For UAE-resident patients, the certified haematology programmes 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 (second-line or later eligibility). - 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 of systemic therapy.

Across all indications:

1. Histological confirmation of B-cell lymphoid malignancy by flow cytometry and immunohistochemistry; CD19 expression typically 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; secondary CNS involvement is reviewed case by case. 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 it. 9. A caregiver commitment for the four-week REMS-restricted period after infusion.

A UAE patient should arrive at the cell therapy referral conversation with the most recent diagnostic workup in hand: histopathology report 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 for LVEF, pulmonary function tests, hepatitis B and C and HIV serology, CMV status, and a current treatment history with response durations to each prior regimen. 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 UAE administration picture, plainly

In 2026 the UAE network of cell therapy centres relevant to commercial Breyanzi includes:

- Cleveland Clinic Abu Dhabi, with the deepest adult cellular therapy programme in the UAE and an established BMT capability. CAR-T programme alignment for commercial CD19 products is active; confirm current authorisation status at intake. - Sheikh Shakhbout Medical City, with an MD Anderson affiliation and an adult haematology service that takes cell therapy referrals. - Abu Dhabi Stem Cells Centre, which coordinated the UAE's first Casgevy gene therapy in April 2026 and is expanding cellular therapy capability. - Burjeel Medical City, with an oncology and BMT programme. - Yas Clinic Hospital Abu Dhabi, which administered the UAE's first Casgevy gene therapy in April 2026 and runs an expanding cell therapy programme that may extend to CD19 CAR-T as authorisation progresses.

For UAE-resident adults where the in-country authorisation timing is incompatible with the disease tempo, the cross-border alternatives include King Faisal Specialist Hospital and Research Centre in Riyadh (the deepest adult CAR-T programme in the Gulf with 200+ commercial CAR-T patients treated since 2020 and an in-house point-of-care CAR-T manufacturing facility opened late 2025), King Hussein Cancer Center in Amman (the largest dedicated cancer centre in MENA with adult cell therapy accreditation), and select European or US centres for patients with international medical coverage.

The 2026 pathway, step by step

Week 0 to 2: Reserve Meds builds the document pack with the treating haematologist's office. We collect the most recent histopathology, imaging, treatment history, and laboratory panels. We submit a first-review request to one or two certified cell therapy centres in parallel so a single slow response does not stall the process.

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; Thiqa coverage for Emirati nationals and Daman or other commercial cover for residents are confirmed at this stage. Out-of-pocket exposure ranges are clarified before commitment.

Week 4 to 5: Apheresis at the certified centre. One to two sessions, outpatient, typically a single half-day. The collected T cells are shipped to BMS for manufacturing.

Week 5 to 8: Manufacturing wait of approximately 24 days. During this window the patient continues bridging therapy under the treating haematologist's direction where the disease tempo warrants. Bridging regimens are physician-choice and depend on prior exposures and refractoriness profile. Reserve Meds coordinates the bridging-therapy logistics where the bridging happens at a centre different from the treating haematologist.

Week 8: Lymphodepletion. Three days of fludarabine plus cyclophosphamide as outpatient or short-stay inpatient.

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 is around day five; median ICANS onset is around day eight. Breyanzi has the most favourable cross-trial CRS profile among CD19 CAR-Ts but the monitoring discipline is the same.

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. Infection precautions. 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 AED

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 in US data. At 2026 indicative cross rates the AED-equivalent product price is approximately AED 1.54 million and the total cost of care band is approximately AED 2.6 to 4.4 million. Outliers run higher when prolonged ICU support or sustained cytopenias drive admission length.

Thiqa coverage for Emirati nationals has historically extended to authorised advanced therapies on a case-by-case basis; the pre-authorisation conversation needs to start before apheresis, not after infusion. Daman and other commercial covers vary in cell therapy coverage; the financial pre-authorisation review at the certified centre is the gating step.

Monitoring through the first year

The first three months after infusion are the highest-acuity period. Cytopenias are common in this window. Infection prophylaxis with antibiotics, antivirals, and antifungals is standard. Transfusion support, growth-factor support, and intravenous immunoglobulin for hypogammaglobulinaemia are often part of the daily picture.

After the first three months, follow-up shifts to monthly disease assessment through the first year and then quarterly. Response assessment is by PET-CT, CT, and disease-specific markers (such as serum protein electrophoresis for any plasmacytic component, or bone marrow biopsy for CLL and MCL). The second primary malignancy surveillance (FDA July 2024 boxed warning across CD19 and BCMA CAR-Ts) extends for 15 years per REMS requirements.

Religious, ethical, and family-logistics framing

Cell-based therapy sits within the Islamic jurisprudential framework that already permits blood transfusion, organ transplantation, and assisted reproduction with appropriate safeguards. Breyanzi is the patient's own T cells engineered ex vivo and re-infused; there is no donor element, no foreign genetic material in the broad sense, and the cells return to a patient whose marrow and immune system remain their own. The dominant ethical frame in MENA Islamic medical ethics for this kind of therapy has been permissive, with the standard expectation that the family makes the treatment decision in consultation with the treating physician and according to the patient's own informed wish.

The family-logistics burden of the four-week REMS-restricted post-infusion period is the practical pressure point. For UAE-resident patients treated locally the logistics are simpler; for patients travelling cross-border to KSA or Jordan, the four-week stay in proximity to the treating centre requires deliberate planning. A caregiver must be present continuously; many UAE families build a rotating caregiver schedule across two or three relatives. Reserve Meds documents the proximity-accommodation, transport, and pharmacy logistics in advance so the family arrives prepared rather than improvising.

When Breyanzi is not the right call

For a UAE 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 and may better fit the disease tempo. For CLL, continued targeted-therapy salvage or a bispecific in development 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. If the conversation with the treating haematologist points toward a different CD19 CAR-T or toward a bispecific, the operational pathway shifts accordingly and we coordinate that pathway instead.

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 UAE Breyanzi case we build the document pack, submit first-review requests to one or two certified centres in parallel, 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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