

Breyanzi

Bahrain · access guide

How to access Breyanzi for relapsed or refractory large B-cell lymphoma, CLL, mantle cell lymphoma, or follicular lymphoma from Bahrain: 2026 pathway via Bahrain haematology centres and cross-border CAR-T programmes

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

Bahrain does not yet have an in-country certified cell therapy centre administering commercial Breyanzi. The practical pathway for a Bahraini adult 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 cross-border to King Faisal Specialist Hospital and Research Centre in Riyadh (the deepest adult CAR-T programme in the Gulf), the National Center for Cancer Care and Research at Hamad Medical Corporation in Doha, the certified centres in Abu Dhabi (Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City), or King Hussein Cancer Center in Amman. Breyanzi NHRA registration status is verified at intake; the named-patient pathway is available where applicable.

This page explains how the pathway works in 2026 for a Bahrain-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 BHD, what insurance and MoH treatment-abroad funding may or may not cover, and what to expect from the four-week REMS-restricted period after infusion.

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, 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 B-cell indications.

For a Bahraini patient with LBCL who has progressed on R-CHOP induction, the TRANSFORM Phase 3 randomised trial 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. For mantle cell lymphoma after BTK failure, Breyanzi and Tecartus are the two licensed CAR-Ts. For follicular lymphoma after two or more lines, TRANSCEND FL showed an overall response rate of 95 percent.

The operational pathway is the same across indications: apheresis, approximately 24 days of manufacturing wait, bridging therapy during the wait, lymphodepletion, single infusion, and the four-week REMS-restricted post-infusion period.

What Breyanzi is, in plain language

A small volume of the patient's own blood is collected by apheresis. The T cells 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. The fractions are expanded separately and recombined 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.

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 CRS and ICANS typically runs around seven days. 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.

Eligibility at a Bahrain haematologist's clinic

Salmaniya Medical Complex, King Hamad University Hospital, BDF Hospital, Bahrain Oncology Center, and the wider Bahraini private-sector haematology network manage the in-country workup and ongoing care. The certified centre that accepts the case applies the FDA and EMA criteria with local adaptation. The eligibility floor varies by indication:

- LBCL: relapsed or refractory after one or more prior lines. - 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. 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. 9. A caregiver commitment for the four-week REMS-restricted period.

A Bahraini 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, PET-CT or CT staging, lactate dehydrogenase, complete blood count, comprehensive metabolic panel, echocardiogram, pulmonary function tests, infectious disease screening, 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 Bahrain administration picture, plainly

Bahrain's National Health Regulatory Authority (NHRA) has had a formal advanced therapy medicinal products framework since 2019. The named-patient mechanism is available for unregistered specialty therapies on a physician-initiated basis where the drug is approved by a recognised reference authority and no clinically suitable locally registered alternative exists.

In practice, Bahrain does not have an in-country certified cell therapy centre administering commercial Breyanzi as of 2026. The regulatory layer matters because it governs the import documentation and the cross-border medical-record exchange. The operational layer is dominated by the destination centre's certification, slot availability, and apheresis-to-infusion logistics.

For most Bahraini families, the practical pathway is one of four destination patterns: 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; the National Center for Cancer Care and Research at Hamad Medical Corporation in Doha; the Abu Dhabi certified centres (Cleveland Clinic Abu Dhabi, Sheikh Shakhboub Medical City) with active 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 Authorized Treatment Centres.

For Bahraini-national families on MoH treatment-abroad funding, the choice of destination centre is often shaped by which regional centre has an existing referral relationship with the MoH international office. For expatriate residents and cash-pay families, the choice is shaped by slot availability, family logistics, and clinician relationship.

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 one or two cross-border centres in parallel.

Week 2 to 4: The destination 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 destination centre. One to two sessions, outpatient.

Week 5 to 8: Manufacturing wait of approximately 24 days. Bridging therapy during this window per treating haematologist's plan in Bahrain or at the destination centre.

Week 8: Lymphodepletion at the destination centre. 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 destination 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, and second-primary malignancies including the class-wide T-cell malignancy signal per the FDA July 2024 boxed warning.

Cost expectation in BHD

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 Bahraini dinars at indicative 2026 cross rates, that is approximately BHD 158,000 for the product alone, with total cost of care commonly BHD 264,000 to BHD 452,000.

For Bahraini-national families on MoH treatment-abroad funding, much of this cost may be underwritten by the public sector. Bahrain's MoH treatment-abroad office maintains existing referral relationships with KFSHRC Riyadh, Cleveland Clinic Abu Dhabi, and selected European centres; confirmation of CAR-T eligibility under treatment-abroad funding runs through your treating haematologist and the MoH referrals office. Reserve Meds does not speculate about MoH financial decisions on a public page.

For expatriate residents and self-pay families, the standard cash-pay-with-documentation pattern applies. Private-insurer coverage for one-time cell therapies in Bahrain remains limited. AXA Gulf, Bahrain National Insurance, GIG Bahrain, and the regional Bupa product handle these cases on a prior-authorisation basis; approval is uncommon outside specific employer-group schemes. We provide the documentation packet that increases approval likelihood.

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

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. Classical analogies extend without difficulty.

The four-week REMS-restricted post-infusion period is the practical pressure point. For patients travelling cross-border to KFSHRC Riyadh, NCCCR Doha, Cleveland Clinic Abu Dhabi, or KHCC Amman, the four-week stay in proximity to the treating centre requires deliberate planning. A caregiver must be present continuously; many Bahraini families build a rotating caregiver schedule across two or three relatives. Reserve Meds documents the proximity-accommodation, transport, and pharmacy logistics in advance.

When Breyanzi is not the right call

For a Bahraini 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. 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.

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 Bahrain Breyanzi case we build the document pack, submit first-review requests to one or two cross-border 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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reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

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