

## Breyanzi

Pakistan · access guide

# Breyanzi access in Pakistan: the DRAP named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

## Quick orientation

Breyanzi (lisocabtagene maraleucel) is an autologous CD19-directed chimeric antigen receptor T-cell therapy approved by the US Food and Drug Administration in February 2021. The label has expanded across diffuse large B-cell lymphoma and other large B-cell lymphomas, chronic lymphocytic leukemia and small lymphocytic lymphoma (March 2024), follicular lymphoma (May 2024), and mantle cell lymphoma (May 2024). The product is manufactured by Bristol-Myers Squibb. The TRANSCEND pivotal trials reported overall response rates of approximately 73 percent with 53 percent complete response in heavily pretreated populations, with a safety profile that shows lower rates of severe cytokine release syndrome than some earlier CD19 CAR-Ts. Breyanzi is not registered with the Drug Regulatory Authority of Pakistan (DRAP), and access for a Pakistani patient runs through the personal-use Special Provision import combined with autologous cell collection at a CAR-T-authorized center.

## Why Pakistani patients ask about Breyanzi

Pakistan's tertiary oncology infrastructure includes Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore and Peshawar, Aga Khan University Hospital in Karachi, Indus Hospital and Health Network in Karachi, Pakistan Atomic Energy Commission Atomic Energy Cancer Hospitals across multiple cities, Jinnah Postgraduate Medical Centre in Karachi, the Children's Hospital and Institute of Child Health in Lahore, and the major private hospitals across Lahore, Karachi, and Islamabad. Several centers run active hematology programs with autologous stem cell transplant capacity. Families arrive at the Breyanzi question after the conventional aggressive B-cell lymphoma sequence has been exhausted: R-CHOP first-line, salvage with R-DHAP or R-ICE followed by autologous stem cell transplant where feasible, and progressively more salvage options. The cost differential between conventional salvage and CAR-T is substantial, and Reserve Meds is candid with Pakistani families about the cash-pay envelope before any commitment.

## **The DRAP named-patient pathway for Breyanzi**

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Pakistan's framework for unregistered-medicine import runs through the Drug Regulatory Authority of Pakistan (DRAP) under the Drugs Act 1976 and DRAP Act 2012. The Special Provision personal-use import is available where a DRAP-licensed physician documents the clinical necessity of a medicine not registered in Pakistan, and where no clinically equivalent locally registered alternative is suitable. For autologous CAR-T cell therapy, the DRAP permit can issue in principle, with operational complexity in infusion-center identification and cell shipment chain of custody.

A complete DRAP application includes the clinical justification letter from the treating hematologist, the physician's Pakistan Medical and Dental Council (PMDC) registration, the destination infusion center identification with FACT or equivalent CAR-T accreditation, the leukapheresis collection plan, the BMS manufacturing slot, and the post-infusion monitoring plan. DRAP Special Provision processing for routine cases is typically 10 to 25 business days. CAR-T cases sit in an 8-to-16-week operational envelope.

## **Where Breyanzi cases are infused for Pakistani patients**

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Pakistan does not currently operate a domestic CAR-T-authorized infusion center. Pakistani families pursuing Breyanzi typically infuse at a US academic medical center (MD Anderson, Memorial Sloan Kettering, Dana-Farber, City of Hope, Moffitt), a European reference center, or a regional Gulf CAR-T hub. King Faisal Specialist Hospital and Research Centre in Riyadh operates an established CAR-T program. Leukapheresis collection can be performed in Pakistan at Shaukat Khanum, AKUH, or another qualified center under chain-of-custody arrangements.

## **Real cost picture for Breyanzi cases**

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US wholesale acquisition cost for Breyanzi is approximately USD 465,000 per dose. The all-in clinical envelope for an international CD19 CAR-T case typically runs USD 650,000 to USD 950,000. The Pakistani rupee trades at approximately 280 PKR to 1 USD with continued volatility, so the drug acquisition cost converts to approximately PKR 130 million at current rates, with the all-in envelope sitting in the PKR 182 million to PKR 266 million band. Cash-pay is the operating assumption. Pakistani private insurance does not routinely reimburse cross-border autologous CAR-T.

## **Typical timeline for Breyanzi in Pakistan**

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End-to-end, a Pakistani Breyanzi case typically runs 12 to 20 weeks from first physician contact to infusion-center discharge: clinical eligibility and infusion-center identification (weeks 1 to 3); DRAP documentation and international travel logistics (weeks 3 to 6); leukapheresis collection and shipment (weeks 6 to 7); BMS manufacturing window (weeks 7 to 12); patient travel and lymphodepleting chemotherapy (week 12 to 13); CAR-T infusion and post-infusion monitoring (weeks 13 to 16); discharge and return to Pakistan (weeks 16 to 20). Manufacturing-failure rate of approximately 5 to 10 percent is a real operational risk.

## What your physician needs to provide

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For a Pakistani hematologist coordinating a Breyanzi case, the clinical justification letter documents the lymphoma subtype with cell-of-origin, MYC and BCL2/BCL6 status where relevant, the prior line-of-therapy summary, current disease burden including imaging, performance status, comorbidity profile, fitness for lymphodepleting chemotherapy, cardiac and pulmonary baseline, and bridging therapy plan. The physician's PMDC registration number, the institutional affiliation, and the Shaukat Khanum or AKUH referral pattern complete the paperwork.

## Common questions about Breyanzi in Pakistan

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**Is the DRAP pathway open for CAR-T?** Yes in principle for the regulatory permit. The operational gate is infusion-center capability.

**Can the collection happen in Pakistan?** Leukapheresis at Shaukat Khanum, AKUH, or another qualified Lahore or Karachi center is operationally feasible under chain-of-custody arrangements.

**What about King Faisal Specialist Hospital in Riyadh?** KFSH-RC operates an established CAR-T program. The decision depends on BMS slot allocation and the visa-and-travel pattern.

**What is the alternative if CD19 CAR-T is not feasible?** Alternatives include the bispecific antibody class (epcoritamab, glofitamab, mosunetuzumab), tafasitamab plus lenalidomide, polatuzumab vedotin combinations, loncastuximab tesirine, and clinical trial enrollment.

**What about Yescarta or Kymriah?** Both are alternative CD19 CAR-Ts. Choice depends on the hematologist's prescription, the lymphoma subtype, and manufacturer slot availability.

**How does long-term follow-up work?** CAR-T REMS requires ongoing monitoring for delayed neurotoxicity, hypogammaglobulinemia, and secondary malignancies. The patient returns to Pakistan with a structured handoff package.

## Where Reserve Meds fits in Breyanzi cases

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Reserve Meds is a US-based concierge coordinator. For Breyanzi cases originating in Pakistan, our role spans US-side sourcing through BMS commercial supply, infusion-center identification and intake c

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### *Reserve Meds's role*

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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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