Breyanzi

Egypt · access guide

Breyanzi access in Egypt: the EDA 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 (initially third-line, then second-line after the TRANSFORM trial in June 2022), 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 pivotal TRANSCEND trials reported overall response rates of approximately 73 percent in large B-cell lymphoma with 53 percent complete response in heavily pretreated populations, and the safety profile shows lower rates of severe cytokine release syndrome than some earlier CD19 CAR-Ts. Breyanzi is not registered with the Egyptian Drug Authority (EDA), and access for an Egyptian patient runs through the personal-use import permit combined with autologous cell collection arranged at a CAR-T-authorised center.

Why Egyptian patients ask about Breyanzi

Egypt has the largest tertiary oncology footprint in North Africa. The National Cancer Institute (NCI) at Cairo University, the 57357 Children's Cancer Hospital, the Naser Institute, Ain Shams University Specialized Hospital, Al-Salam International Hospital, As-Salam Specialised Hospital, Cairo University Hospitals (Kasr Alainy), Magrabi Cancer Centre, and the El-Gouna Hospital network all carry hematology-oncology programs. Several centers run autologous stem cell transplant programs that approach the operational complexity of CAR-T. Families arrive at the Breyanzi question after the conventional aggressive B-cell lymphoma sequence has been exhausted: R-CHOP or dose-adjusted EPOCH-R first-line, salvage with R-DHAP, R-ICE, or R-GDP followed by autologous stem cell transplant, and progressively more salvage with polatuzumab vedotin combinations, tafasitamab plus lenalidomide, or loncastuximab tesirine. For relapsed CLL, the conversation comes after BTK inhibitors and venetoclax-based combinations.

The EDA named-patient pathway for Breyanzi

Egypt's regulatory framework for unregistered-medicine import runs through the Egyptian Drug Authority (EDA) under Decree No. 425 of 2009 and subsequent EDA regulations. The personal-use import permit is available where an EDA-licensed physician documents the clinical necessity of a medicine not registered or not available in Egypt, and where no clinically equivalent locally registered alternative is suitable. For autologous CAR-T cell therapy, the EDA permit can issue in principle, with the operational complexity sitting in infusion-center identification and cell shipment chain of custody rather than in the regulatory paperwork.

A complete EDA application includes the clinical justification letter from the treating hematologist documenting the prior treatment course, refractory status, and CD19 CAR-T rationale; the treating physician's EDA medical license verification (Egyptian Medical Syndicate registration); the destination infusion center identification with FACT or equivalent CAR-T accreditation; the leukapheresis collection plan; the BMS manufacturing slot reservation; and the post-infusion monitoring plan with the local Egyptian hematologist. EDA processing for routine personal-use cases is typically 10 to 20 business days. CAR-T cases sit in an 8-to-16-week operational envelope.

Where Breyanzi cases are infused for Egyptian patients

Egypt does not currently operate a domestic CAR-T-authorised infusion center. Egyptian 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 where compassionate-use access is available, 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 Egypt at the NCI or a qualified Cairo center under chain-of-custody arrangements, with the apheresis product shipped to the BMS manufacturing facility.

Real cost picture for Breyanzi cases

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 depending on infusion-center fee schedule, length of post-infusion stay, and whether complications require ICU support. The Egyptian pound trades at approximately 48 to 50 EGP to 1 USD, so the drug acquisition cost converts to approximately EGP 22.3 million to EGP 23.2 million at current rates. The all-in envelope sits in the EGP 31 million to EGP 47.5 million band. Cash-pay is the operating assumption; private insurance reimbursement of cross-border autologous CAR-T is not a routine line item in the Egyptian market.

Typical timeline for Breyanzi in Egypt

End-to-end, an Egyptian 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); EDA documentation and international travel logistics (weeks 3 to 6); leukapheresis collection and shipment to the US (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 Egypt (weeks 16 to 20). Manufacturing-failure rate of approximately 5 to 10 percent is a real operational risk.

What your physician needs to provide

For an Egyptian 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 pulmona

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