Breyanzi

Nepal · access guide

Breyanzi access in Nepal: the DDA 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 TRANSFORM 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. TRANSCEND data report overall response rates of approximately 73 percent with 53 percent complete response in heavily pretreated populations. Breyanzi is not registered with Nepal's Department of Drug Administration (DDA), and access for a Nepali patient runs through the personal-use import permit combined with autologous cell collection arranged at a CAR-T-authorised center.

Why Nepali patients ask about Breyanzi

Nepal's tertiary oncology infrastructure is concentrated at Bir Hospital, Bhaktapur Cancer Hospital, B.P. Koirala Memorial Cancer Hospital in Bharatpur, Tribhuvan University Teaching Hospital in Kathmandu, Patan Hospital, and the major private hospitals (Norvic International Hospital, Grande International Hospital, HAMS Hospital, Vayodha Hospital). Autologous stem cell transplant capacity is limited and most complex hematology cases are referred to India under the SAARC referral pattern, particularly to Tata Memorial Centre in Mumbai, AIIMS Delhi, CMC Vellore, Apollo Cancer Institute, and Kokilaben Dhirubhai Ambani Hospital. Families arrive at the Breyanzi question after exhausting the conventional aggressive B-cell lymphoma sequence, and the realistic conversation is about cross-border infusion almost universally.

The DDA named-patient pathway for Breyanzi

Nepal's framework for unregistered-medicine import runs through the Department of Drug Administration (DDA) under the Drugs Act 1978 and DDA regulations. The personal-use import permit is available where a DDA-licensed physician documents clinical necessity. For autologous CAR-T cell therapy, the DDA permit can issue in principle, with operational complexity in infusion-center identification and cell shipment chain of custody. Nepali patients are often referred to Indian tertiary centers, in which case the regulatory permit is sometimes coordinated through the receiving Indian center's CDSCO Rule 36 framework rather than DDA.

A complete DDA application includes the clinical justification letter, the physician's Nepal Medical Council registration, the destination infusion center identification, the leukapheresis collection plan, the BMS manufacturing slot, and the post-infusion monitoring plan. DDA processing for routine cases is typically 10 to 20 business days.

Where Breyanzi cases are infused for Nepali patients

Nepal does not currently operate a domestic CAR-T-authorised infusion center. Nepali families pursuing Breyanzi typically infuse at an Indian academic medical center where CAR-T capability has been stood up (Tata Memorial Centre Mumbai, Apollo Cancer Institute Chennai or Hyderabad, Kokilaben Mumbai, BLK Max Super Speciality Hospital Delhi), a US academic medical center (MD Anderson, Memorial Sloan Kettering, Dana-Farber, City of Hope, Moffitt), or a European reference center. The India-route is operationally and culturally easier for many Nepali families. Leukapheresis collection can be performed in Nepal at a qualified Kathmandu center or in India.

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 if infusion is in the US or Europe; the India-route envelope is materially lower at USD 250,000 to USD 450,000 inclusive of drug, infusion-center fees, accommodation, and ground logistics, though the precise numbers depend on the Indian center and the case complexity. The Nepali rupee trades at approximately 135 NPR to 1 USD, so the drug acquisition cost converts to approximately NPR 62.7 million at current rates. Cash-pay is the operating assumption.

Typical timeline for Breyanzi in Nepal

End-to-end, a Nepali 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); DDA documentation and 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 Nepal (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 a Nepali hematologist coordinating a Breyanzi case, the clinical justification letter documents the lymphoma subtype with cell-of-origin, MYC and BCL2/BCL6 status where relevant, 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 Nepal Medical Council number, the institutional affiliation, and the receiving Indian or US center referral letter complete the paperwork.

Common questions about Breyanzi in Nepal

Is the India-route the realistic option? For most Nepali families, yes. India operates established CAR-T programs at multiple centers, and the cost differential vs. US infusion is substantial.

Can the collection happen in Nepal? Leukapheresis at a qualified Kathmandu center is operationally feasible under chain-of-custody arrangements; collection at the receiving Indian center is simpler.

What about Tata Memorial Centre? TMC operates a deep myeloma and lymphoma program with growing CAR-T capability. The cost profile is meaningfully lower than US infusion.

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. Indian centers may have differential access to specific products.

How does long-term follow-up work? CAR-T REMS requires ongoing monitoring. The patient returns to Nepal with a structured handoff package to the local hematologist.

Where Reserve Meds fits in Breyanzi cases

Reserve Meds is a US-based concierge coordinator. For Breyanzi cases originating in Nepal, our role focuses on US-side sourcing where the US-route is chosen, infusion-center identification and intake coordination, leukapheresis collection logistics, DDA documentation packet for your physician, international travel and accommodation coordination, and a single named coordinator. Where the case routes to India, we coordinate with the receiving Indian center on the operational handoff. No prior Reserve Meds Breyanzi case experience is logged yet at the Nepal-origin profile.

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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