Breyanzi

India · access guide

Breyanzi access in India: the CDSCO named-patient pathway

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

Quick orientation

Breyanzi (lisocabtagene maraleucel) is a CD19-directed autologous chimeric antigen receptor (CAR) T-cell therapy from Bristol Myers Squibb, first approved by the US FDA in February 2021 for adults with relapsed or refractory large B-cell lymphoma. The label has subsequently expanded through several supplemental approvals: second-line large B-cell lymphoma (June 2022), chronic lymphocytic leukaemia and small lymphocytic lymphoma after at least two prior lines including a BTK inhibitor and a BCL-2 inhibitor (March 2024), follicular lymphoma (May 2024), mantle cell lymphoma (May 2024), and marginal zone lymphoma (May 2024). Breyanzi uses a defined 1:1 CD4 to CD8 CAR-T cell composition and a 4-1BB co-stimulatory domain. The product is under FDA REMS for CRS, ICANS, and prolonged cytopenias. Indian families pursuing Breyanzi through the named-patient pathway are typically working around one of three local gaps: the drug is not registered in India at all, or it is registered but not currently stocked, or it is registered and stocked but the patient is unable to clear payer or formulary requirements within a clinically acceptable timeframe. Reserve Meds coordinates the US-side sourcing through a DSCSA-compliant specialty channel, the cold-chain (or, where applicable, cryogenic) logistics, and the documentation packet your physician submits to the Central Drugs Standard Control Organisation (CDSCO).

Why India patients need Breyanzi through the named-patient pathway

India's pharmaceutical regulatory landscape is administered by the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare. The Drugs and Cosmetics Act 1940 and the New Drugs and Clinical Trials Rules 2019 establish the framework for marketing authorisation, personal-use import, and patient-specific access. Despite India's status as a global generics manufacturer, originator specialty biologics, CAR-T cell therapies, and newer monoclonal antibodies frequently reach Indian patients through cross-border named-patient routes before local launch or after local stockouts. Large B-cell lymphoma in the relapsed or refractory setting after first-line R-CHOP-based therapy has historically been associated with poor outcomes through autologous stem cell transplant and chemotherapy salvage. The introduction of CD19-directed CAR-T cell therapies has transformed this landscape: Yescarta (axicabtagene ciloleucel) was first FDA-approved in October 2017, Kymriah (tisagenlecleucel) in May 2018 for adult DLBCL, and Breyanzi in February 2021. All three are now approved in second-line LBCL, and Breyanzi has uniquely expanded into CLL/SLL, follicular lymphoma, mantle cell lymphoma, and marginal zone lymphoma, giving it the broadest indication breadth of the CD19 CAR-T class.

For Breyanzi specifically, three converging patterns drive India cases. First, indication or product lag. Originator specialty medicines like Breyanzi (lisocabtagene maraleucel) reach local registration in India months to years after FDA approval, and in many cases the FDA-labelled indication, the specific product configuration, or the manufacturing slot for the patient is not locally available. Second, payer or formulary constraint. Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Max Bupa (Niva Bupa), and corporate group policies each assess high-cost specialty therapies case by case, and a patient who clinically fits the FDA label can still face an uncovered claim or a step-therapy denial that consumes weeks the disease will not wait through. Third, brand-specific clinical reasoning. The treating haematologist-oncologist with cellular therapy experience may have made a deliberate decision based on the patient's phenotype, prior-therapy exposure, or comorbidity profile, and substituting a different molecule simply because it is what the local pharmacy stocks is not the right clinical call.

In each pattern, the named-patient pathway is the legal mechanism that connects a India-licensed physician's clinical decision with US-sourced, FDA-labeled product for a specific identified patient. It is not a workaround; it is the framework the regulator has established for precisely these gaps.

The CDSCO named-patient pathway for Breyanzi

The Indian framework for patient-specific import of an unregistered medicine is the personal-use import permission under Rule 36 of the New Drugs and Clinical Trials Rules 2019, combined with the personal-import exemption under the Drugs and Cosmetics Rules. CDSCO grants permission for a treating physician at a registered hospital to import a specific medicine for a specific named patient when the medicine is approved by a stringent regulatory authority (US FDA, EMA, MHRA, PMDA, Health Canada, or TGA) and no clinically equivalent registered alternative is suitable. Applications route through the CDSCO SUGAM portal (cdscoonline.gov.in). For Breyanzi specifically, the clinical justification typically frames the case around the precise FDA-approved indication and the documented gap in the local route.

A complete application includes a clinical justification letter from the treating physician (diagnosis, severity, prior therapies, why this specific drug, why the locally stocked option is not suitable for this case), the treating physician's license verification through the State Medical Council of the practising state and the Medical Council of India / National Medical Commission, an anonymised patient identifier where the CDSCO submission allows, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity requested, intended treatment duration), the destination dispensing facility name, license number, and pharmacy or cell-therapy laboratory in charge, and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing facility, including cold-chain or cryogenic handling specific to the product format.

Breyanzi is indicated across multiple B-cell malignancies: relapsed or refractory large B-cell lymphoma (including diffuse large B-cell lymphoma not otherwise specified, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL transformed from indolent lymphoma) after one or more prior lines of therapy, relapsed or refractory chronic lymphocytic leukaemia or small lymphocytic lymphoma after at least two prior lines including a BTK inhibitor and a BCL-2 inhibitor, relapsed or refractory follicular lymphoma after two or more prior lines, relapsed or refractory mantle cell lymphoma after two or more prior lines including a BTK inhibitor, and relapsed or refractory marginal zone lymphoma after two or more prior lines. The clinical justification for Breyanzi typically documents the specific indication criterion that the patient meets, the prior-therapy history that establishes label eligibility, and the operational plan at the treating hospital.

CDSCO routine processing for Rule 36 personal-import applications is typically 15 to 30 business days from complete submission. Complex cases (CAR-T, first-of-kind biologics, gene therapy) can extend to 8 to 12 weeks. State drug controller endorsement adds a few additional days. CDSCO retains discretion on timing.

Where Breyanzi gets dispensed in India

A focused group of India institutions handle named-patient imports of high-acuity specialty products as established workflow, with the in-house clinical, pharmacy, and (where relevant) cell-therapy laboratory infrastructure and haematologist-oncologists experienced with both the clinical management and the CDSCO application set. Apheresis logistics, lymphodepletion with fludarabine and cyclophosphamide, CRS monitoring (Lee criteria grading and tocilizumab availability), ICANS monitoring (ICE score and corticosteroid escalation), cytopenia management beyond day 28, infection prophylaxis, REMS-trained dispensing centre, and a minimum 4-week local availability requirement for the treating patient after infusion are the operational pillars of a Breyanzi case. Outpatient administration is increasingly common at experienced centres for selected patients.

Tertiary and major private hospitals that have demonstrated the capability for Breyanzi-class therapy in India include Tata Memorial Hospital (Mumbai, India's flagship cancer centre and the country's deepest CAR-T and stem-cell transplant programme), Tata Memorial Centre's ACTREC at Kharghar, All India Institute of Medical Sciences (AIIMS Delhi) oncology and bone marrow transplant programme, Apollo Cancer Centres (Chennai, Delhi, Hyderabad), Christian Medical College Vellore oncology, Postgraduate Institute of Medical Education and Research (PGIMER Chandigarh), Kidwai Memorial Institute of Oncology (Bangalore), Medanta The Medicity oncology and bone marrow transplant unit, Fortis Memorial Research Institute (Gurugram), and HCG Cancer Centres across Bangalore, Ahmedabad, and other metros.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a licensed pharmaceutical establishment or a tertiary referral hospital that holds the necessary CDSCO relationship and files the application on the prescribing physician's behalf. The medicine then moves into the treating hospital's pharmacy under documented chain-of-custody.

Real cost picture for Breyanzi in India

US WAC for Breyanzi is approximately USD 465,000 for the single Breyanzi infusion (one-time treatment), with total cost of care (including apheresis, lymphodepletion, hospitalisation or extended outpatient monitoring, supportive care for CRS or ICANS, and post-infusion monitoring) typically running USD 650,000 to USD 1,300,000 depending on hospital pricing and complication profile. The INR/USD conversion (INR floats; reference rate approximately 83 INR per USD as of early 2026) means the US WAC for the single Breyanzi infusion alone translates to roughly INR 3.86 crore at reference INR rates, with total cost of care for a complete CAR-T episode often INR 5.4 to 10.8 crore at reference rates. These figures are US WAC reference points only; manufacturer pricing on cross-border named-patient supply may differ from US WAC, and Reserve Meds' firm quote on a specific case reflects negotiated supply pricing rather than US list.

International logistics for a cold-chain biologic shipment to India typically runs USD 600 to USD 2,200 (approximately INR 50,000 to INR 180,000) depending on destination city, urgency, and pack size. CDSCO and customs fees on personal-import medicines are generally nominal on physician-attested medical necessity; cell and gene therapy shipments require additional CITES/quarantine clearance for cryogenic dewars. For Breyanzi specifically, CAR-T cell product shipping is materially different from a vialed biologic. Apheresis material moves from the treating hospital to the manufacturing facility (Bristol Myers Squibb's network in the United States) under temperature-controlled conditions, and the engineered cell product returns in a cryogenic liquid-nitrogen dewar (-150 degrees Celsius vapour phase) with continuous temperature logging, GPS tracking, and a tightly choreographed thaw-and-infuse window measured in hours, not days. Hospital pharmacy and cell-therapy laboratory accreditation, FACT or equivalent infrastructure, REMS-trained staff, ICU access, and tocilizumab availability are non-negotiable. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, Indian health insurers assess named-patient imports case by case. The Insurance Regulatory and Development Authority of India (IRDAI) has not mandated coverage of cross-border imported medicines, and most policies exclude or sub-limit specialty biologics and cellular therapies. Corporate group policies and high-net-worth retail policies sometimes cover named-patient imports under exception requests. The Pradhan Mantri Jan Arogya Yojana and CGHS schemes do not extend to imported originator biologics. For a one-time CAR-T therapy versus a continuous biologic, the coverage conversation looks very different: an indefinite biologic creates an ongoing claim cycle, while a CAR-T case is a single-event, high-acuity claim that some insurers will treat under exceptional-care provisions. We do not promise coverage from any insurer; we supply the documentation set that lets your insurer assess the case.

Typical timeline for Breyanzi in India

CDSCO routine processing for a Breyanzi application from a complete submission typically tracks the regulator's standard window. For Breyanzi specifically, the manufacturing or sourcing pathway adds an additional dimension beyond the regulator timeline. CAR-T cell therapy is not an off-the-shelf biologic: once the apheresis is scheduled and performed, the manufacturer requires approximately 4 weeks to engineer, expand, and quality-release the autologous cell product. Pre-apheresis bridging therapy, lymphodepletion timing, and the manufacturing slot together define the critical path. End-to-end, from first regulatory submission to infusion, a Breyanzi case is typically 8 to 14 weeks at experienced centres. The 4-week minimum post-infusion local monitoring requirement adds another month of in-country presence after the infusion itself.

We do not promise specific case timelines. Central Drugs Standard Control Organisation (CDSCO) retains discretion on application review, manufacturers retain discretion on slot allocation and supply, and shipping lanes are subject to customs and weather. The figures above describe typical experience at experienced centres, not contractual commitments.

What your physician needs to provide

For a India-licensed haematologist-oncologist with cellular therapy experience prescribing Breyanzi through the CDSCO pathway, the clinical justification letter is the cornerstone of the application. For Breyanzi, the clinical justification letter typically documents the patient's specific B-cell malignancy diagnosis with histology and immunophenotype, cell-of-origin classification where relevant (germinal centre B-cell-like vs activated B-cell-like for DLBCL), prior lines of therapy with response and duration, current disease status (relapsed or refractory by Lugano or iwCLL or relevant criteria), and the precise prior-therapy criteria that establish FDA-label eligibility for the specific indication being pursued. The letter specifies the planned apheresis date, lymphodepletion regimen, planned infusion date, the inpatient or outpatient monitoring plan (Breyanzi is increasingly administered outpatient at experienced centres for selected patients), and the local monitoring commitment.

The physician's State Medical Council registration number and treating hospital CDSCO/state drug controller registration, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. For products requiring cell-therapy laboratory infrastructure, the facility's FACT or equivalent accreditation status, the cryogenic storage capability, and the trained-personnel attestation typically attach to the application as supporting documentation. Reserve Meds supplies a template clinical justification letter populated with the FDA-label criteria, the prior-therapy framing, and the chain-of-custody specifics; the treating physician edits to the patient's actual case and signs.

Common questions about Breyanzi in India

Will my India insurer cover this? On the insurance side, Indian health insurers assess named-patient imports case by case. The Insurance Regulatory and Development Authority of India (IRDAI) has not mandated coverage of cross-border imported medicines, and most policies exclude or sub-limit specialty biologics and cellular therapies. Corporate group policies and high-net-worth retail policies sometimes cover named-patient imports under exception requests. The Pradhan Mantri Jan Arogya Yojana and CGHS schemes do not extend to imported originator biologics. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital. We do not promise coverage from any insurer.

How does Breyanzi compare to Yescarta and Kymriah for large B-cell lymphoma? All three are CD19-directed CAR-T products approved for adult relapsed or refractory large B-cell lymphoma. Yescarta (Kite / Gilead) uses a CD28 co-stimulatory domain. Kymriah (Novartis) and Breyanzi (BMS) use 4-1BB co-stimulatory domains. Breyanzi's defined 1:1 CD4 to CD8 composition is a manufacturing signature. Comparative efficacy is roughly similar across the class in DLBCL, with somewhat different toxicity timing. Breyanzi has the broadest indication breadth, covering CLL/SLL, follicular lymphoma, mantle cell lymphoma, and marginal zone lymphoma in addition to LBCL.

Is Breyanzi a one-time infusion? Yes. Breyanzi is a single infusion of engineered autologous CAR-T cells. Long-term monitoring continues but no repeat infusion is given. Post-CAR-T relapse pathways depend on disease biology and patient fitness.

Can Breyanzi be given outpatient? Yes, at experienced centres. Breyanzi's relatively delayed and lower-incidence CRS profile (compared to CD28-co-stimulatory products) supports outpatient administration in selected fit patients with reliable caregiver support and close hospital proximity. Outpatient pathways require a tightly coordinated infusion centre and rapid-admission protocols.

What is the CLL/SLL second-line consideration? Breyanzi's March 2024 approval for CLL/SLL after BTK inhibitor and BCL-2 inhibitor failure is the first CAR-T approval in CLL. The label requires at least two prior lines including a BTK inhibitor (such as ibrutinib, acalabrutinib, or zanubrutinib) and a BCL-2 inhibitor (venetoclax). Patient selection involves disease burden, fitness, and a careful CRS and ICANS risk assessment given the older CLL population.

What about subsequent therapy after Breyanzi relapse? Options after CD19 CAR-T relapse depend on the underlying disease, the duration of remission, and CD19 expression status. For LBCL, options include bispecific antibodies (glofitamab, epcoritamab), polatuzumab-vedotin based regimens, autologous or allogeneic stem cell transplant in fit patients, and clinical trials. For CLL, ibrutinib-based or venetoclax-based combinations may still have residual activity, and bispecific or non-CD19 antigen targets are options. Reserve Meds coordinates whichever subsequent product the haematologist prescribes.

How long must the patient remain near the treating hospital? The FDA REMS and treatment protocols call for the patient to remain within close range (typically within driving distance) of the treating hospital for at least 4 weeks after infusion for CRS and ICANS surveillance, and to avoid driving for at least 8 weeks. International patients plan extended local stays accordingly.

What about competing products in this class? Within CD19 CAR-T for B-cell lymphoma, Yescarta (axicabtagene ciloleucel) from Kite / Gilead and Kymriah (tisagenlecleucel) from Novartis are the principal alternatives. Bispecific antibodies (glofitamab, Columvi; epcoritamab, Epkinly) are off-the-shelf alternatives that avoid the manufacturing wait. Polatuzumab vedotin and antibody-drug conjugate-based regimens fill the third-line or salvage space for non-CAR-T-candidate patients. Choice depends on disease, prior therapy, fitness, manufacturing slot, and prescriber judgment. Reserve Meds coordinates whichever specific product the treating physician has prescribed.

Where Reserve Meds fits in Breyanzi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your haematologist-oncologist with cellular therapy experience, we do not replace the Central Drugs Standard Control Organisation (CDSCO), and we do not replace your dispensing pharmacy or treating hospital. For Breyanzi specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated cold-chain or cryogenic logistics with continuous temperature logging into India, and assign a single named coordinator through the case.

For CAR-T cases specifically, our coordinator role spans the apheresis-to-infusion arc rather than a single shipment: manufacturing slot communication with the haematologist-oncologists, apheresis-collection logistics, cryogenic shipment of the engineered cell product, infusion-day coordination, and post-infusion monitoring milestones. No prior Reserve Meds case experience for Breyanzi is logged yet; standard NPP coordination under our cellular-therapy playbook applies.

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.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.
reservemeds.com · hello@reservemeds.com