Aucatzyl

India · access guide

Aucatzyl access in India: the CDSCO named-patient pathway

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

Quick orientation

Aucatzyl (obecabtagene autoleucel) is an autologous CD19-directed chimeric antigen receptor (CAR) T-cell therapy developed by Autolus Therapeutics, approved by the US FDA in November 2024 for adults with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (B-ALL). The therapy uses a fast off-rate CD19 binder designed to reduce the depth and duration of CAR-T-cell engagement with target cells, with the aim of mitigating the cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) toxicity that has historically constrained CD19 CAR-T use in adult B-ALL. In the pivotal FELIX trial, Aucatzyl produced durable remissions with a notably lower rate of severe (grade 3 or higher) CRS and ICANS than prior CD19 CAR-T constructs in adult B-ALL. The FDA approval is notable for not requiring REMS, in part on the basis of that toxicity profile. Indian families pursuing Aucatzyl 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 Aucatzyl 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. B-cell acute lymphoblastic leukaemia in adults has historically had worse outcomes than in children, with 5-year overall survival in the relapsed or refractory setting measured in single digits with conventional chemotherapy. The introduction of CD19-directed therapy, first with the bispecific T-cell engager blinatumomab and the antibody-drug conjugate inotuzumab ozogamicin, then with CD19 CAR-T cell therapies (tisagenlecleucel, brexucabtagene autoleucel), and now with Aucatzyl, has progressively reshaped the treatment paradigm. Aucatzyl in particular addresses a long-standing gap: a CD19 CAR-T product specifically engineered to fit adult B-ALL where CRS and ICANS toxicity have been the dose-limiting factors.

For Aucatzyl specifically, three converging patterns drive India cases. First, indication or product lag. Originator specialty medicines like Aucatzyl (obecabtagene autoleucel) 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 Aucatzyl

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 Aucatzyl 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.

Aucatzyl is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia. The therapy targets CD19, a cell-surface protein expressed on the B-cell lineage including B-ALL blasts. Like other CAR-T cell therapies, Aucatzyl is autologous: the patient's own T cells are collected by apheresis, engineered ex vivo to express the CD19-targeting CAR construct, expanded over approximately 4 weeks at the manufacturing facility, and infused back into the patient after lymphodepleting chemotherapy. The clinical justification for Aucatzyl 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 Aucatzyl 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), B-cell aplasia management with immunoglobulin replacement, minimum 4-week local availability requirement for the treating patient after infusion, and CNS prophylaxis review where applicable are the operational pillars of an Aucatzyl case. The lower-toxicity profile in the pivotal FELIX trial does not eliminate the need for inpatient monitoring at a CAR-T-capable centre.

Tertiary and major private hospitals that have demonstrated the capability for Aucatzyl-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 Aucatzyl in India

US WAC for Aucatzyl is approximately USD 525,000 for the single Aucatzyl infusion (one-time treatment), with total cost of care (including apheresis, lymphodepletion, hospitalisation, supportive care for CRS or ICANS, and post-infusion monitoring) typically running USD 750,000 to USD 1,500,000 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 Aucatzyl infusion alone translates to roughly INR 4.36 crore at reference INR rates, with total cost of care for a complete CAR-T episode often INR 6.2 to 12.5 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 Aucatzyl specifically, CAR-T cell product shipping is materially different from a vialed biologic. Apheresis material moves from the treating hospital to the manufacturing facility (typically in the United Kingdom or United States in Aucatzyl's case, depending on the manufacturing slot) 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, trained staff for CAR-T administration, ICU access, and tocilizumab and corticosteroid availability remain non-negotiable, even with Aucatzyl's reduced toxicity profile. 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 Aucatzyl in India

CDSCO routine processing for a Aucatzyl application from a complete submission typically tracks the regulator's standard window. For Aucatzyl 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 Aucatzyl 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 Aucatzyl through the CDSCO pathway, the clinical justification letter is the cornerstone of the application. For Aucatzyl, the clinical justification letter typically documents the patient's adult B-ALL diagnosis with cytogenetic risk profile (Philadelphia chromosome status, MLL rearrangement, other high-risk features), prior lines of therapy with response and duration (typically prior induction and consolidation, prior salvage with blinatumomab or inotuzumab where applicable, and allogeneic stem cell transplant status), current disease status (relapsed or refractory by standard criteria), and the FDA-label indication criteria. The letter specifies the planned apheresis date, lymphodepletion regimen, planned infusion date, the inpatient hospitalisation plan with ICU access and tocilizumab availability, and the post-infusion monitoring plan including B-cell aplasia management and immunoglobulin replacement.

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 Aucatzyl 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 Aucatzyl compare to Kymriah and Tecartus for adult B-ALL? Kymriah (tisagenlecleucel) is FDA-approved for paediatric and young adult (up to 25 years) B-ALL. Tecartus (brexucabtagene autoleucel) is FDA-approved for adults with relapsed or refractory B-ALL. Aucatzyl (November 2024) is also FDA-approved for adults with relapsed or refractory B-ALL, with the distinguishing feature of a fast off-rate CD19 binder that reduced grade 3+ CRS and ICANS rates substantially in the pivotal FELIX trial. The choice between Aucatzyl and Tecartus depends on toxicity considerations, manufacturing slot availability, and the prescriber's experience.

Is Aucatzyl under FDA REMS like other CAR-T products? No. The FDA approved Aucatzyl in November 2024 without a Risk Evaluation and Mitigation Strategy programme, in part on the basis of the reduced rates of severe CRS and ICANS observed in the FELIX trial. This is operationally significant: the treating centre still requires CAR-T infrastructure, but the formal REMS designation that has accompanied prior CD19 CAR-T products is absent.

What about CD19 antigen loss and post-CAR-T relapse? CD19 antigen loss is a recognised mechanism of relapse after CD19-directed CAR-T therapy. Approximately 10 to 30 percent of post-CAR-T relapses in B-ALL involve CD19-negative disease. Subsequent options include CD22-directed therapy, allogeneic stem cell transplant, blinatumomab, inotuzumab, or enrolment in clinical trials of dual-targeted or alternative-antigen CAR-T constructs.

How long does the patient need to stay near the treating hospital? The post-infusion monitoring requirement for Aucatzyl is similar to other CAR-T products: typically a minimum of 4 weeks within driving distance of the treating hospital for CRS and ICANS surveillance. International patients accordingly plan an extended local stay; this is the dominant logistical determinant of an Aucatzyl case.

Will the patient need allogeneic stem cell transplant after Aucatzyl? Whether to consolidate the CAR-T response with allogeneic stem cell transplant in adult B-ALL is an active clinical question without a single right answer. Many treating centres pursue consolidation with allo-SCT in fit patients with high-risk disease and an available donor; others observe with minimal residual disease monitoring. The haematologist makes this decision case by case.

Is Aucatzyl available for paediatric patients? No. The FDA approval is for adults. Paediatric and young adult patients (up to 25 years) with relapsed or refractory B-ALL fall within the Kymriah label.

What about competing products in this class? Within CD19 CAR-T for adult relapsed or refractory B-ALL, Tecartus (brexucabtagene autoleucel) from Kite Pharma / Gilead is the principal alternative. Kymriah (tisagenlecleucel) from Novartis is the paediatric and young adult option. Bispecific T-cell engagers (blinatumomab, Blincyto) and antibody-drug conjugates (inotuzumab ozogamicin, Besponsa) remain widely used in earlier lines and as bridging therapy. Choice depends on disease biology, prior therapy exposure, fitness, manufacturing slot, and prescriber judgment. Reserve Meds coordinates whichever specific product the treating physician has prescribed.

Where Reserve Meds fits in Aucatzyl 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 Aucatzyl 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 Aucatzyl 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.

reservemeds.com · hello@reservemeds.com