Abecma

Pakistan · access guide

Abecma access in Pakistan: the DRAP named-patient pathway

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

Quick orientation

Patients in Pakistan access Abecma (idecabtagene vicleucel) for relapsed or refractory multiple myeloma through the DRAP named-patient mechanism, filed by a PMDC-licensed physician for a specific named patient. Because Abecma requires REMS-certified administration, the realistic path often combines named-patient sourcing with coordinated travel; Reserve Meds handles US sourcing, logistics, and timeline planning end to end.

Why Pakistan patients need Abecma through the named-patient pathway

Pakistan's pharmaceutical regulatory environment is administered by the Drug Regulatory Authority of Pakistan (DRAP) established under the DRAP Act 2012. DRAP administers marketing authorisations, GMP inspections, pharmacovigilance, and the personal-import pathway through which named-patient cross-border shipments are processed. Pakistan's pharmaceutical market relies heavily on generics and originator products manufactured under licence locally; many originator specialty biologics, CAR-T therapies, and newer monoclonal antibodies are not registered domestically and reach Pakistani patients through cross-border named-patient routes. Multiple myeloma is the second most common haematological malignancy worldwide. Despite three or four lines of contemporary therapy (proteasome inhibitors such as bortezomib, immunomodulatory drugs such as lenalidomide and pomalidomide, anti-CD38 antibodies such as daratumumab and isatuximab, and emerging bispecific antibodies), median survival after triple-class refractory disease historically measured in months rather than years. CAR-T cell therapy, first with anti-CD19 constructs for lymphoma and leukaemia and now with anti-BCMA constructs for myeloma, represents a paradigm shift in cellular immunotherapy.

For Abecma specifically, three converging patterns drive Pakistan cases. First, indication or product lag. Originator specialty medicines like Abecma (idecabtagene vicleucel) reach local registration in Pakistan 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. Jubilee General, EFU Life, Adamjee Insurance, IGI Life, 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 Pakistan-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 DRAP named-patient pathway for Abecma

The Pakistani framework for patient-specific import of an unregistered medicine is the personal-use import permission issued by DRAP under the Drugs Act 1976 and the DRAP Act 2012, with the personal baggage allowance for limited quantities and the formal personal-import licence for larger or higher-acuity shipments. DRAP 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 recognised regulatory authority (US FDA, EMA, MHRA, PMDA, Health Canada, or TGA) and no equivalent registered alternative is suitable. Applications route through the DRAP online system or directly to the Licensing Division. For Abecma 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 Pakistan Medical and Dental Council (PMDC, now PMC), an anonymised patient identifier where the DRAP 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.

Abecma is indicated for the treatment of adults with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The therapy targets BCMA, a cell-surface protein highly expressed on plasma cells and multiple myeloma cells. The clinical justification for Abecma 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.

DRAP routine processing for personal-use import permission is typically 15 to 30 business days from a complete submission. Complex first-time imports of cell or gene therapies and high-acuity biologics can extend to 8 to 12 weeks. State Bank of Pakistan foreign-exchange release for the underlying purchase can add additional time.

Where Abecma gets dispensed in Pakistan

A focused group of Pakistan 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 DRAP 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, and a minimum 4-week local availability requirement for the treating patient after infusion are the operational pillars of an Abecma case.

Tertiary and major private hospitals that have demonstrated the capability for Abecma-class therapy in Pakistan include Shaukat Khanum Memorial Cancer Hospital and Research Centre (Lahore and Peshawar, the country's leading dedicated cancer hospital), Aga Khan University Hospital (Karachi) oncology and bone marrow transplant, Armed Forces Bone Marrow Transplant Centre (AFBMTC Rawalpindi), Indus Hospital oncology programme, Children's Hospital Lahore paediatric oncology, Jinnah Postgraduate Medical Centre Karachi, and Shifa International Hospital (Islamabad) oncology.

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 DRAP 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 Abecma in Pakistan

US WAC for Abecma is approximately USD 419,500 for the single Abecma infusion (one-time treatment), with total cost of care (including apheresis, lymphodepletion, hospitalisation, ICU support, tocilizumab and corticosteroids for CRS or ICANS, and post-infusion monitoring) typically running USD 600,000 to USD 1,200,000 depending on hospital pricing and complication profile. The PKR/USD conversion (PKR floats with periodic interventions; reference rate approximately 280 PKR per USD as of early 2026, with material range due to FX volatility) means the US WAC for the single Abecma infusion alone translates to roughly PKR 117 million at reference PKR rates (subject to material FX variance), with total cost of care for a complete CAR-T episode often PKR 168 to 336 million at current FX 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 Pakistan typically runs USD 500 to USD 2,000 (approximately PKR 140,000 to PKR 560,000 at current FX, subject to fluctuation) depending on destination city, urgency, and pack size. DRAP permit fees are nominal relative to drug cost; physician-attested medical necessity typically clears customs duty on personal-import medicines. For Abecma 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 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, Pakistani health insurers assess named-patient imports case by case. Coverage for cross-border originator specialty biologics is limited, with most cash-pay families relying on direct out-of-pocket payment. Corporate group policies and high-net-worth retail policies occasionally cover named-patient imports under exception requests. The Sehat Sahulat Programme and provincial health card 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 Abecma in Pakistan

DRAP routine processing for a Abecma application from a complete submission typically tracks the regulator's standard window. For Abecma 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 Abecma 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. Drug Regulatory Authority of Pakistan (DRAP) 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 Pakistan-licensed haematologist-oncologist with cellular therapy experience prescribing Abecma through the DRAP pathway, the clinical justification letter is the cornerstone of the application. For Abecma, the clinical justification letter typically documents the patient's multiple myeloma diagnosis with ISS or R-ISS stage, cytogenetic risk (including high-risk features such as del(17p), t(4;14), t(14;16), 1q gain or amplification, or extramedullary disease), prior lines of therapy with response and duration, current disease status (relapsed or refractory by IMWG criteria), and the precise prior-therapy criteria that establish FDA-label eligibility (at least two prior lines including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody for the expanded April 2024 label). The letter specifies the planned apheresis date, the lymphodepletion regimen (fludarabine 30 mg/m2 plus cyclophosphamide 300 mg/m2 daily for 3 days), the planned infusion date, and the inpatient hospitalisation plan with ICU access, tocilizumab availability, and a minimum 4-week local monitoring commitment.

The physician's PMC registration number and treating hospital DRAP/provincial 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 Abecma in Pakistan

Will my Pakistan insurer cover this? On the insurance side, Pakistani health insurers assess named-patient imports case by case. Coverage for cross-border originator specialty biologics is limited, with most cash-pay families relying on direct out-of-pocket payment. Corporate group policies and high-net-worth retail policies occasionally cover named-patient imports under exception requests. The Sehat Sahulat Programme and provincial health card 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.

Is Abecma a one-time infusion? Yes. Abecma is a single infusion of engineered autologous CAR-T cells. Unlike continuous biologic therapy that requires regular dosing for years, the CAR-T product is administered once after lymphodepleting chemotherapy. Long-term disease monitoring, infection surveillance, immunoglobulin replacement when needed, and surveillance for late effects continue, but no repeat infusion of Abecma is given.

What is the difference between Abecma and Carvykti? Both are BCMA-directed CAR-T therapies for relapsed or refractory multiple myeloma. Abecma (Bristol Myers Squibb and 2seventy bio) uses an idecabtagene vicleucel construct with a 4-1BB co-stimulatory domain. Carvykti (Johnson and Johnson / Legend Biotech) uses ciltacabtagene autoleucel with a bivalent BCMA-binding domain. Clinical outcomes, side-effect profiles, and manufacturing windows differ. Choice depends on prescriber judgment, manufacturing slot availability, and patient-specific factors. Reserve Meds coordinates whichever product the haematologist has prescribed.

What does CRS mean and is it dangerous? Cytokine release syndrome (CRS) is a systemic inflammatory response triggered by CAR-T activation. It typically develops in the first 1 to 14 days after infusion and ranges from mild fever to severe haemodynamic instability requiring ICU care. The Lee grading scale guides management; tocilizumab (anti-IL-6 receptor) is the first-line pharmacological treatment, with corticosteroids escalated as needed. Modern centres manage CRS routinely; the FDA REMS programme exists specifically because the therapy requires trained handling.

What if the cells fail to expand or the patient relapses? Manufacturing failure (out-of-specification product) and post-infusion relapse are both real outcomes. Manufacturing failure rates have improved substantially since launch; modern figures are in the low single digits at experienced centres. Post-infusion relapse pathway depends on disease biology, duration of remission, and patient fitness. Subsequent options can include bispecific BCMA-CD3 antibodies (such as teclistamab or elranatamab), CD38-directed therapy, repeat CAR-T with a different construct if appropriate, or clinical-trial enrolment.

Can the apheresis be done in our country and shipped to the United States? In principle yes; in practice, the apheresis-manufacturer chain of custody is tightly controlled, and most international cases are routed through a contracted apheresis centre at the manufacturing partner's network. A subset of high-volume international centres has direct collection-and-ship arrangements. The treating haematologist works with the manufacturer to confirm which apheresis pathway applies to a specific case.

How long must the patient stay near the treating hospital after infusion? FDA REMS and treatment protocols require 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 accordingly plan an extended local stay; this is the single largest logistical determinant of Abecma case planning.

What about competing products in this class? In BCMA-directed CAR-T, Carvykti (ciltacabtagene autoleucel) from Johnson and Johnson / Legend Biotech is the principal competitor. In BCMA bispecific antibodies, teclistamab (Tecvayli), elranatamab (Elrexfio), and talquetamab (Talvey, targeting GPRC5D rather than BCMA but in the same competitive niche) sit alongside CAR-T as off-the-shelf alternatives that avoid the manufacturing wait and the autologous logistics. Choice depends on disease biology, prior therapy exposure, fitness, and prescriber judgment. Reserve Meds coordinates whichever specific product the treating physician has prescribed.

Where Reserve Meds fits in Abecma 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 Drug Regulatory Authority of Pakistan (DRAP), and we do not replace your dispensing pharmacy or treating hospital. For Abecma 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 Pakistan, 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 Abecma 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