Tecvayli access in Pakistan

A BCMA-by-CD3 bispecific T-cell engager for relapsed or refractory multiple myeloma, reached through the Drug Regulatory Authority of Pakistan Special Permission pathway.

Quick orientation

Tecvayli (teclistamab-cqyv) is a humanised IgG4 bispecific antibody that simultaneously binds B-cell maturation antigen (BCMA) on multiple myeloma cells and CD3 on T cells, redirecting host T-cell cytotoxicity against the malignant plasma cell clone. It is the first BCMA-by-CD3 bispecific T-cell engager approved for multiple myeloma. The US FDA granted accelerated approval on October 25, 2022 and converted to traditional approval on March 5, 2026, with a same-day combination indication approved with daratumumab and hyaluronidase-fihj for relapsed or refractory multiple myeloma after at least one prior line. For Pakistani families whose hematologist-oncologist has documented relapsed or refractory disease after at least four prior lines for monotherapy, or at least one prior line for the daratumumab combination, the lawful route is the Drug Regulatory Authority of Pakistan Special Permission for Personal Use Import (the NOC), filed through the OIES portal. Reserve Meds coordinates DSCSA-compliant US sourcing through the REMS-certified channel, validated cold-chain logistics to Karachi or Lahore, and the documentation kit your hematologist-oncologist needs. Clinical decisions stay with your treating physician and the inpatient hematology unit. Reserved for you.

Why patients in Pakistan need Tecvayli via the named-patient pathway

Multiple myeloma patients in Pakistan who have cycled through proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody therapy reach the end of the standard triple-class line and need a sequencing option. BCMA-by-CD3 bispecific therapy is a key sequencing option after a patient has progressed on BCMA-directed CAR-T (such as Carvykti or Abecma) or for patients who are ineligible for CAR-T because of disease tempo, organ function, or the absence of an accessible CAR-T capable center in country.

The Tecvayli access pattern in Pakistan typically combines two conditions. Tecvayli may have directional regional registration through Janssen affiliates serving the Gulf and South Asia, but it is not consistently stocked at the Pakistani treating hospital's pharmacy, and the hospital's formulary listing or local reimbursement does not include the product. The DRAP Special Permission framework exists for this scenario: the lawful route to import an unregistered or locally unavailable medicine for a specific named patient. Janssen's Tecvayli withMe and Janssen Patient Assistance Foundation are explicitly US-only and do not extend to international named-patient cases. The DRAP pathway is the answer.

The DRAP named-patient pathway for Tecvayli

DRAP, established under the Drug Regulatory Authority of Pakistan Act 2012 and reporting to the Federal Ministry of National Health Services, Regulations and Coordination, regulates the import of medicines through the QA&LT Division's Import and Export Section. For unregistered or locally unavailable medicines required by a specific named patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import.

Institutional applications for hospital-administered biologics are filed by the dispensing hospital's import pharmacy through the OIES portal.

The application package for a Tecvayli case typically includes the clinical justification letter from the treating hematologist-oncologist on hospital letterhead, the oncologist's PMDC licence verification, the patient identifier (CNIC for adult patients or passport for foreign nationals receiving treatment in Pakistan), product details (Tecvayli brand name, teclistamab-cqyv INN, manufacturer of record Janssen Biotech Inc., 30 mg/3 mL or 153 mg/1.7 mL single-dose vial, requested quantity calculated from patient body weight for the step-up sequence and the maintenance schedule), the destination dispensing facility licence including inpatient hematology capability for 48-hour observation, a US specialty wholesaler letter confirming sourcing through the REMS-certified channel and DSCSA-compliant chain-of-custody back to Janssen, and a chain-of-custody plan from the US source through international shipment with continuous 2 to 8 degrees Celsius temperature monitoring to the dispensing facility.

The clinical-justification angle specific to Tecvayli is the prior-line documentation, the REMS-equivalent institutional capability statement, and the cytokine release syndrome plus immune effector cell-associated neurotoxicity surveillance plan. The letter typically documents the multiple myeloma diagnosis with ISS/R-ISS staging, cytogenetics, the prior lines of therapy with named medicines and documented outcomes (for the monotherapy indication, at least four prior lines including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody; for the daratumumab combination indication, at least one prior line including a proteasome inhibitor and immunomodulatory agent), and the clinical rationale for a BCMA-by-CD3 bispecific. The dosing plan reflects the FDA label: Step-up Dose 1 of 0.06 mg/kg subcutaneously on Day 1, Step-up Dose 2 of 0.3 mg/kg on Day 4 with 2 to 7 day separation, First Treatment Dose of 1.5 mg/kg on Day 7 with 2 to 7 day separation, then 1.5 mg/kg once weekly maintenance until progression or unacceptable toxicity, with the option to transition to 1.5 mg/kg every two weeks after sustained complete response of at least six months per the 2024 label update.

The REMS-equivalent statement is the differentiating element. The US Tecvayli REMS does not extend extraterritorially in a formal sense, but DRAP reviewers will look for evidence that the receiving Pakistani institution can manage CRS (reported in up to 72 percent of patients in MajesTEC-1, predominantly grade 1 or 2 and concentrated around the step-up doses) and ICANS (reported in approximately 6 percent of patients). The letter calls out pre-medications (corticosteroid, antihistamine, and antipyretic 1 to 3 hours prior to each step-up dose and the first full treatment dose) and the requirement for 48-hour inpatient observation after each of those four doses. The combination indication adds daratumumab and hyaluronidase-fihj per the updated package insert.

Routine DRAP personal-use cases typically clear in four to eight weeks. Complex cases involving REMS-certified channels, cold-chain biologics, and inpatient observation protocols can extend to ten to sixteen weeks at first authorisation. A first BCMA-by-CD3 bispecific case at a given Pakistani institution may take longer because the reviewer scrutinises the CRS/ICANS readiness in detail. Reserve Meds plans on the longer end. DRAP reserves discretion.

Where Tecvayli gets dispensed in Pakistan

Tecvayli is a 2 to 8 degrees Celsius cold-chain biologic that requires an institutional setting capable of step-up dose administration, 48-hour inpatient observation after each of the three step-up doses and after the first full treatment dose, CRS escalation pathway, ICANS neurologic monitoring with baseline and serial exams through Cycle 2, hypogammaglobulinemia and

infection surveillance, and immunoglobulin replacement in selected patients. The dispensing facility shortlist is therefore narrow.

The Pakistani institutions that handle DRAP named-patient imports as routine workflow and have hematology-oncology bone marrow transplant-capable infrastructure suited for Tecvayli include Aga Khan University Hospital in Karachi (the Department of Oncology with established hematology and bone marrow transplant capability and a 24/7 institutional pharmacy with temperature-controlled storage), Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore (Pakistan's flagship cancer hospital with outpatient and inpatient pharmacy services and adult hematology-oncology capability), the Indus Hospital and Health Network in Karachi with strong oncology, hematology, and pediatric capability across its tertiary referral network, and Liaquat National Hospital in Karachi. AKUH and SKMCH&RC are the natural primary fits for adult Tecvayli cases given the BMT-capable infrastructure and the established import pharmacy workflow.

For patients whose treating hematologist-oncologist is at a regional hospital outside Karachi, Lahore, or Islamabad, the practical route is to coordinate with one of the major centers above as the dispensing and inpatient observation facility while the treating physician retains clinical oversight, with the medicine routed to the receiving inpatient-capable hematology unit under continuous temperature monitoring. The Combined Military Hospitals network with tertiary capacity at CMH Rawalpindi and CMH Lahore handles cases for military families and referred civilians.

Real cost picture for Tecvayli in Pakistan

Reserve Meds quotes Pakistani cases in USD and accepts USD wire transfers from any USD-accessible source, which matters for the multi-cycle continuous duration of Tecvayli therapy. The transparent cost build has three line items.

First, the underlying US drug cost. Tecvayli's US wholesale acquisition cost is approximately USD 9,478 per weekly dose on a weighted average across the 30 mg and 153 mg vial sizes, with a weighted average of approximately USD 10,521 per treatment vial reported in independent pharmacoeconomic literature. For a typical 85 kg patient on weekly maintenance dosing, the published 12-month drug cost is approximately USD 427,210, before any administration, monitoring, or inpatient observation costs associated with step-up dosing and before any rebates or assistance. Course total scales with body weight, dose schedule (weekly versus every two weeks after sustained complete response), and treatment duration, which is open-ended until progression or unacceptable toxicity. Second, international cold-chain logistics from US specialty wholesaler to Karachi, Lahore, or Islamabad with continuous 2 to 8 degrees Celsius temperature monitoring and validated qualified shipper, which typically runs USD 800 to USD 1,500 per shipment. Third, regulatory documentation handling at the Pakistani end, the Reserve Meds concierge fee, and the 48-hour inpatient observation cost following each step-up dose and the first full treatment dose (a separate hospital-side fee that does not flow through Reserve Meds).

Currency context. The Pakistani Rupee traded near PKR 278 to 280 per USD in early May 2026, with annual CPI inflation at 10.9 percent in April 2026. Quoting in USD protects the family from PKR volatility. Many Pakistani families fund Tecvayli through pooled resources across overseas relatives in Saudi Arabia, the UAE, the UK, and North America. On the insurer side, Adamjee Health Insurance and Jubilee Personal HealthCare cover in-hospital chemotherapy in some formularies, but specialty imports of FDA-approved-but-not-locally-registered or unstocked BCMA bispecifics are typically outside formulary. Some plans assess case-by-case. Sehat

Sahulat's Rs. 1,000,000 per family per year ceiling does not stretch to cover a continuous Tecvayli course. Cash-pay is the default operating posture.

Typical timeline for Tecvayli in Pakistan

End to end, a routine Tecvayli case at a tertiary cancer center with established DRAP personal-import workflow, REMS-equivalent CRS/ICANS readiness, and cold-chain biologic handling capability typically clears six to twelve weeks of DRAP review for the first cycle, plus five to ten business days for US specialty wholesale intake through the REMS-certified channel and outbound preparation, plus four to seven days for cold-chain international transit and FBR Customs clearance at Karachi, Lahore, or Islamabad airport. That puts a realistic end-to-end planning window of eight to fourteen weeks for the first step-up dose. After the step-up sequence and first full treatment dose are completed under inpatient observation, the weekly maintenance shipments can be planned on a rolling cadence with each shipment timed to the every-week or, after sustained complete response, every-two-week dosing rhythm. The cold-chain leg adds two to three days versus an ambient shipment. Continuity of supply is the operational priority because Tecvayli is given until disease progression or unacceptable toxicity.

What your physician needs to provide

The cornerstone document is the clinical justification letter, original and stamped on hospital letterhead, signed by the treating hematologist-oncologist under their active PMDC licence. For Tecvayli, the letter typically covers the multiple myeloma diagnosis with ISS/R-ISS staging and cytogenetic risk, the prior lines of therapy with named regimens and documented outcomes (proteasome inhibitor, immunomodulatory agent, anti-CD38 monoclonal antibody for the monotherapy line count, plus BCMA-directed CAR-T history where applicable), and the clinical rationale for a BCMA-by-CD3 bispecific.

The dosing plan is stated (Step-up Dose 1 of 0.06 mg/kg subcutaneously on Day 1, Step-up Dose 2 of 0.3 mg/kg on Day 4 with 2 to 7 day separation, First Treatment Dose of 1.5 mg/kg on Day 7 with 2 to 7 day separation, then 1.5 mg/kg weekly maintenance, with transition to every two weeks after sustained complete response of at least six months per the label option), with pre-medications listed (corticosteroid, antihistamine, antipyretic 1 to 3 hours prior to each step-up dose and the first full treatment dose) and the required 48-hour inpatient observation after each of those four doses called out explicitly. The monitoring plan covers CRS surveillance with the wallet card provided to the patient, ICANS neurologic exams at baseline, before, and after each step-up dose and through Cycle 2, CBC and infection surveillance, immunoglobulin monitoring with replacement therapy in selected patients given hypogammaglobulinemia risk, and the criteria for dose hold or discontinuation per the FDA label. The combination indication adds the daratumumab and hyaluronidase-fihj regimen detail. The treating oncologist's PMDC licence must be active for the full requested course. The dispensing facility's institutional licence must cover inpatient hematology with 48-hour observation capability and the cold-chain handling protocol. Reserve Meds supplies the documentation kit including the DRAP Pharmacovigilance Centre adverse-event reporting reference; Reserve Meds does not file adverse-event reports, that responsibility sits with the treating clinician.

Common questions about Tecvayli in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Tecvayli?
Coverage of named-patient imports of unregistered or unstocked BCMA bispecifics is uncommon across Pakistani health plans. Some insurers assess case-by-case where the multiple myeloma

diagnosis and prior triple-class exposure are fully documented. Reserve Meds supplies the documentation a family or hospital needs to file a claim. The realistic default is cash-pay.

How does Sehat Sahulat interact with this?
The Rs. 1,000,000 per family per year ceiling does not stretch to cover a continuous Tecvayli course. Families who qualify can still use Sehat Sahulat for hospitalisation, supportive care, and inpatient observation costs while Tecvayli procurement runs cash-pay in parallel at the inpatient hematology unit.

Why Tecvayli versus CAR-T?
Tecvayli is an off-the-shelf biologic with a defined step-up schedule and continuous dosing, suitable for patients who cannot wait for CAR-T manufacturing, who lack access to a CAR-T center in Pakistan or regionally, or who have progressed after CAR-T. Carvykti or Abecma may offer deeper, time-limited responses but require apheresis, bridging therapy, and a slot at a qualified cellular therapy center. The decision rests with your treating hematologist-oncologist.

What about the CRS and ICANS risk?
Cytokine release syndrome was reported in up to 72 percent of patients in MajesTEC-1, predominantly grade 1 or 2 and concentrated around the step-up doses. ICANS was reported in approximately 6 percent of patients. The FDA label requires 48-hour inpatient observation after each of the three step-up doses and after the first full treatment dose. This is why the receiving Pakistani institution must have the inpatient hematology capability and the CRS escalation pathway in place. Your hematologist-oncologist counsels the family on the full safety profile before starting therapy.

Is Tecvayli appropriate for first-line multiple myeloma?
The monotherapy label is restricted to heavily pretreated patients with at least four prior lines including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody. The newer combination indication with daratumumab and hyaluronidase-fihj allows use after at least one prior line. Earlier-line use outside these label parameters is not on-label.

Can my family member receive Tecvayli at home?
No. Tecvayli requires an institutional setting with inpatient observation capability for the step-up doses and first full treatment dose, with ongoing oncology care at the inpatient hematology unit for the weekly or every-two-week maintenance schedule.

Our family is split between Pakistan and the Gulf. Can you coordinate in both places?
Yes. Reserve Meds runs the patient-side coordination in Urdu and English with a single named coordinator running the case end to end across the UAE, Saudi Arabia, the UK, North America, and elsewhere where relatives are pooling USD.

Where Reserve Meds fits in Tecvayli cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist-oncologist, we do not replace DRAP, we do not replace your dispensing inpatient hematology unit, we do not provide REMS certification, and we do not act as a Pakistani importer of record. For a Tecvayli case in Pakistan, we orchestrate the DSCSA-compliant US specialty wholesale procurement through a REMS-certified channel with full serial traceability back to Janssen, prepare the documentation kit your hematologist-oncologist needs for the DRAP Special Permission filing through the OIES portal (including the REMS-equivalent institutional readiness statement on CRS/ICANS management and 48-hour inpatient observation), coordinate validated 2 to 8 degrees Celsius cold-chain international shipping with continuous temperature monitoring

through Karachi, Lahore, or Islamabad airport, and stay with the case through the step-up sequence and weekly or every-two-week maintenance reorders under a single named coordinator in English and Urdu. Reserve Meds has documented named-patient access pathways for Tecvayli in India, Saudi Arabia, the UAE, and Qatar; Pakistan joins that pattern. AKUH and SKMCH&RC are the primary fit for adult cases. Clinical decisions remain with your hematologist-oncologist. Regulatory authority remains DRAP. Dispensing and inpatient observation remain with the licensed Pakistani institution.

Next step

If your family is exploring Tecvayli for an adult relative whose hematologist-oncologist has documented relapsed or refractory multiple myeloma after at least four prior lines including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 antibody (or at least one prior line for the daratumumab combination indication), and the receiving Pakistani institution has CRS/ICANS readiness and 48-hour inpatient observation capability, the next step is to join the waitlist. We will confirm eligibility and case fit within 24 to 48 hours, send a documentation kit to your treating hematologist-oncologist in English with Urdu-language family-facing summaries where requested, and align with your dispensing institution on the OIES filing.

Reserved for you.

Related

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- DRAP Personal Use Import pathway
- Tecvayli in Saudi Arabia
- Tecvayli in the UAE
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- Multiple myeloma condition page

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