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Tecvayli access in Egypt

A BCMA-by-CD3 bispecific T-cell engager for relapsed or refractory multiple myeloma, reached through the Egyptian Drug Authority Personal Importation pathway.

Quick orientation

Tecvayli (teclistamab-cqyv) is a humanized 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. In Egypt, Tecvayli may not be consistently stocked at the treating hospital pharmacy even where directionally registered through Janssen affiliates, and named-patient inquiry from Egyptian families whose treating hematologist-oncologist has exhausted standard triple-class therapy is established. The lawful route is the EDA Personal Importation pathway, supported by a DSCSA-compliant US specialty wholesale chain certified under the Tecvayli REMS and named-patient documentation prepared in coordination with the dispensing institution. Reserve Meds coordinates the US sourcing, the cold-chain logistics to Cairo International Airport, and the documentation kit your physician will need, while clinical decisions stay with your treating hematologist-oncologist. Reserved for you.

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

Multiple myeloma patients in Egypt who have cycled through proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody therapy are in a population where the standard local formulary options run thin. 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 Egypt typically combines two conditions. Either the drug is not consistently stocked at the treating hospital pharmacy even where Janssen affiliate registration has progressed regionally, or the hospital's formulary listing or local reimbursement does not include the product, leaving cash-pay families to source it themselves through a named-patient channel. The EDA Personal Importation framework, codified by Law No. 151 of 2019, is the lawful route when a recognised reference authority (US FDA, EMA, MHRA, PMDA Japan, or Health Canada) has approved a medicine and no clinically equivalent locally registered alternative is suitable or available for the named patient. Janssen's withMe and Janssen Patient Assistance Foundation US patient support programs do not extend to international cases.

The EDA named-patient pathway for Tecvayli

The Egyptian Drug Authority (EDA) was created by Law No. 151 of 2019, with executive regulations issued under Prime Minister Decision No. 777 of 2020. EDA permits importation of unregistered or locally-unavailable medicines for a specific named patient where no equivalent

registered product is available locally, or where the available quantity of an equivalent locally registered product cannot meet the patient's clinical need. The pathway is commonly referred to as Personal Importation and described in EDA correspondence as Special Access or Compassionate Use for novel oncology biologics.

For a Tecvayli case, applications are filed through the dispensing institution's import pharmacy. The standard package includes the clinical justification letter from the treating hematologist-oncologist on hospital letterhead (the multiple myeloma diagnosis with ISS/R-ISS staging, cytogenetics, the prior lines of therapy with named medicines and documented outcomes including at least four prior lines containing a proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody for the monotherapy indication, or at least one prior line containing a proteasome inhibitor and immunomodulatory agent for the daratumumab/hyaluronidase-fihj combination indication, the clinical rationale for a BCMA-by-CD3 bispecific, the requested dose, planned schedule, and projected duration), a recent prescription specifying brand name (Tecvayli), generic name (teclistamab-cqyv), strength (30 mg/3 mL or 153 mg/1.7 mL single-dose vial), and the per-cycle quantity calculated from patient body weight, the patient identifier copy (national ID card or passport), the treating oncologist's Egyptian Medical Syndicate membership number and Ministry of Health licence reference, product details (Janssen Biotech, Inc. as US manufacturer of record; country of origin; FDA approval reference; shelf life; cold-chain storage at 2 to 8 degrees Celsius protected from light in original carton; not to be frozen or shaken), the destination dispensing facility licence including the receiving institution's capability for 48-hour inpatient observation, and a chain-of-custody plan with continuous temperature monitoring through Cairo International Airport.

The clinical-justification angle specific to Tecvayli is the REMS-equivalent institutional capability statement plus prior-line documentation. The US Tecvayli REMS does not extend extraterritorially in a formal sense, but EDA reviewers will look for evidence that the receiving Egyptian institution can manage cytokine release syndrome (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 immune effector cell-associated neurotoxicity syndrome (ICANS, reported in about 6 percent of patients). The dosing plan is weight-based and subcutaneous (Step-up Dose 1 of 0.06 mg/kg 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). Pre-medications (corticosteroid, antihistamine, and antipyretic 1 to 3 hours prior) and the requirement for 48-hour inpatient observation after each step-up dose and after the first full treatment dose belong in the same letter. The combination indication adds daratumumab and hyaluronidase-fihj per the updated package insert.

Routine EDA personal-import authorisations for well-documented complex oncology biologic cases typically process in a 3 to 6 week window once a complete package is submitted, with complex cases involving cold-chain biologics and inpatient observation protocols extending to 6 to 12 weeks. A first BCMA-by-CD3 bispecific case at a given institution may take longer because the reviewer will scrutinise the CRS/ICANS readiness in detail. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

Where Tecvayli gets dispensed in Egypt

Tecvayli is a 2 to 8 degree Celsius cold-chain biologic that requires an institutional setting capable of step-up dose administration, 48-hour inpatient observation after each step-up dose

and the first full treatment dose, CRS escalation pathway, ICANS neurologic monitoring with baseline and serial exams through Cycle 2, and hypogammaglobulinemia and infection surveillance. The dispensing-facility shortlist is therefore narrow. The Egyptian institutions that handle EDA named-patient imports as routine workflow and have hematology-oncology BMT-capable infrastructure include Cairo University Hospitals (Kasr Al Ainy) with its dedicated hematology and bone marrow transplant programs, Ain Shams University Hospitals with its strong hematology service, Dar Al Fouad Hospital in 6th of October City (JCI-accredited, with over 250 bone marrow transplants completed, part of the Alameda Healthcare Group), As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group with multi-site oncology infrastructure. Children's Cancer Hospital Egypt 57357 is the pediatric oncology reference center and is not the routing for adult Tecvayli cases.

For patients whose treating hematologist-oncologist is at a regional hospital outside Cairo, Giza, or Alexandria, the practical route is to partner with a Cairo-based licensed specialty importer that handles the EDA filing and cold-chain customs clearance through Cairo International Airport, with delivery to the receiving inpatient-capable hematology unit under continuous temperature monitoring. The importer holds the dispensing pharmacy licence; the clinical justification letter still originates with the treating hematologist-oncologist.

Real cost picture for Tecvayli in Egypt

Reserve Meds quotes Egyptian cases in USD and accepts USD wire transfers. The transparent cost build for a Tecvayli case 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 pharmaco-economic 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. Second, international cold-chain logistics from US source to Cairo International Airport with continuous 2 to 8 degree Celsius temperature monitoring and validated qualified shipper, which typically runs USD 800 to USD 1,500 per shipment. Third, regulatory documentation handling fees at the Egyptian end and the Reserve Meds concierge fee, itemised on the firm quote rather than bundled. The 48-hour inpatient observation cost following each step-up dose and the first full treatment dose is a separate hospital-side fee that does not flow through Reserve Meds.

Many Egyptian families coordinate USD funds through relatives in the Gulf, the UK, or North America, which is helpful given the EGP has lost more than 70 percent of its value against the US dollar since early 2022 (USD/EGP near 52 to 53 in May 2026 per IMF Article IV consultation). On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, and Allianz Egypt handle named-patient imports case by case, with private plans more likely to engage where relapsed or refractory multiple myeloma is a documented covered indication. Misr Insurance and Orient Takaful may engage on selected cases. UHIA coverage of specialty imports remains constrained across most governorates in the current rollout phase. Cash-pay is the default operating posture; reimbursement, where it applies, is sought after delivery through the patient or hospital's claim.

Typical timeline for Tecvayli in Egypt

End to end, a routine Tecvayli case at a tertiary cancer center with established EDA personal-import workflow, REMS-equivalent CRS/ICANS readiness, and cold-chain biologic handling capability typically clears 3 to 6 weeks of EDA review for the first cycle, plus three to seven days

for US specialty wholesale intake through the REMS-certified channel, preparation, and outbound, plus four to seven days for cold-chain international transit and customs clearance at Cairo International Airport. That puts a realistic end-to-end planning window of five to ten 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 align with 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 because of the validated shipper qualification, temperature data logger configuration, and customs documentation. Continuity of supply is the operational priority because Tecvayli is given until disease progression or unacceptable toxicity with no fixed course length.

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 Egyptian Medical Syndicate membership and Ministry of Health 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, and where applicable BCMA-directed CAR-T history), and the clinical rationale for a BCMA-by-CD3 bispecific. The dosing plan is stated (Step-up Dose 1 of 0.06 mg/kg 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 under the REMS framework, 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 EMS membership and Ministry of Health licence must be active for the full requested treatment course. The dispensing facility's institutional licence must cover inpatient hematology with 48-hour observation capability and the cold-chain handling protocol. Public-sector hematologists at Kasr Al Ainy and Ain Shams, and private-sector hematologists at Dar Al Fouad, As-Salam, and similar institutions have signing authority on EDA personal-import clinical justification letters. Reserve Meds supplies the physician documentation kit, including the Egyptian Pharmacovigilance Center (EPVC) adverse-event reporting reference. Reserve Meds does not file adverse-event reports; that responsibility sits with the treating clinician under their Egyptian licence.

Common questions about Tecvayli in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover Tecvayli?

Each insurer assesses named-patient imports case by case. Because relapsed or refractory multiple myeloma after triple-class exposure is a documented covered category, some plans engage more readily, particularly for the established lines criteria. Pre-authorisation is the norm.

Reserve Meds supplies the documentation an insurer needs; the claim filing remains with the patient or hospital. Cash-pay is the default posture for cross-border access.

Does UHIA cover Tecvayli?

Not as a general rule. The UHIA rollout is phased through 2032 and does not currently cover most specialty named-patient biologics.

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 Egypt 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 Egyptian institution must have the inpatient hematology capability and the CRS escalation pathway in place. Your hematologist-oncologist will counsel the family on the full safety profile before starting.

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 for the weekly or every-two-week maintenance schedule.

Our family is split between Cairo and the Gulf. Can you coordinate in both places?

Yes. Reserve Meds runs the patient-side coordination in Arabic where requested and the family-side coordination in English in parallel, with a single named coordinator running the case end to end across the UAE, Saudi Arabia, the UK, North America, and elsewhere.

Where Reserve Meds fits in Tecvayli cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist-oncologist, do not replace EDA, do not replace your dispensing inpatient hematology unit, we do not provide REMS certification, and we do not act as an Egyptian importer of record. For a Tecvayli case in Egypt, 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 EDA Personal Importation filing including the REMS-equivalent institutional readiness statement on CRS/ICANS management and 48-hour inpatient observation, coordinate cold-chain international shipping with continuous temperature monitoring and validated qualified shippers through Cairo International 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 Arabic. Reserve Meds has documented

named-patient access pathways for Tecvayli in India, Saudi Arabia, UAE, and Qatar through the country cell pages, with inquiry-stage demand observed from oncology referrers in the region; Egypt joins that pattern. Clinical decisions remain with your hematologist-oncologist. The regulatory authority remains EDA. The dispensing and inpatient observation remain with the licensed Egyptian institution.

Next step

If your family is exploring Tecvayli for a 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 Egyptian 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 Arabic-language family-facing summaries where requested, and align with your institution's import pharmacy or with a Cairo-based licensed specialty importer on the EDA filing.

Reserved for you.

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