Tecvayli access in UAE: the EDE named-patient pathway

How patients in the United Arab Emirates access Tecvayli (teclistamab-cqyv) for relapsed or refractory multiple myeloma, the first BCMA by CD3 bispecific T-cell engager approved by the FDA, via the EDE unregistered-medicine import permit and a REMS-equivalent treatment-centre framework.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Tecvayli is the brand name for teclistamab-cqyv, 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 25 October 2022 for adults with relapsed or refractory disease after at least four prior lines, and converted that to traditional approval on 5 March 2026. On the same date the FDA also approved teclistamab in combination with daratumumab and hyaluronidase-fihj for adults with at least one prior line including a proteasome inhibitor and an immunomodulatory agent. UAE patients access Tecvayli through the Emirates Drug Establishment unregistered-medicine import permit and a REMS-equivalent treatment-centre framework that the dispensing hospital coordinates with the manufacturer's representatives. Reserved for you.

Why patients in the UAE need Tecvayli via a named-patient pathway

International patients pursue Tecvayli via named-patient or personal-import pathways for four overlapping reasons. First, in some target countries Tecvayli is not yet locally registered or is registered but not stocked at the treating centre, leaving a real gap between label availability and patient-level access. Second, in countries where Tecvayli is registered, formulary listing or reimbursement may exclude it, leaving cash-pay families to source it themselves. Third, 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 lack of access to a CAR-T capable centre. Fourth, families with the means to coordinate cross-border access are willing to source US-channel supply to a qualified treating physician overseas when the local channel is constrained.

In the UAE specifically, Tecvayli may be locally registered or in transition through Janssen's UAE affiliate channels, but availability at the treating centre, formulary listing, and out-of-pocket affordability vary. Where the local channel does not deliver, the EDE pathway with US-sourced supply remains a documented legal route.

The EDE named-patient pathway for Tecvayli, with REMS-equivalent treatment-centre framework

The federal pathway is the unregistered-medicine import permit. MOHAP historically administered the framework, and from 29 December 2025 the Emirates Drug Establishment took over 44 core services under Federal Decree-Law No. 38 of 2024, including marketing authorisations, import and export permits, pharmacovigilance oversight, and personal-use import permits. EDE filings flow through ede.gov.ae. The framework allows licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority and a clinically equivalent locally registered alternative is not suitable.

Tecvayli sits at the more complex end of this pathway because of the US Risk Evaluation and Mitigation Strategy (REMS). In the United States, healthcare providers must be specially certified under the Tecvayli REMS, and pharmacies plus the healthcare settings that prepare and dispense Tecvayli must also be REMS-certified. The UAE does not operate the FDA REMS programme, but the treating UAE hospital and the prescribing haematologist-oncologist effectively replicate the REMS conditions: certified handling capability, inpatient observation infrastructure for the step-up doses, the cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) management protocol, and the patient wallet card. The clinical justification letter and the dispensing-facility documentation state this expressly so the EDE submission shows the cause for confidence that the receiving institution can administer the drug safely.

For a Tecvayli submission, the clinical justification letter centres on the relapsed or refractory multiple myeloma diagnosis, the prior-line history (at least four prior lines including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody for the monotherapy indication; at least one prior line for the new combination indication with daratumumab and hyaluronidase-fihj), and the rationale for a BCMA bispecific at this point in the sequence. Where the patient has progressed on BCMA-directed CAR-T (Carvykti or Abecma) or is ineligible for CAR-T because of disease tempo, organ function, or access constraints, that context is documented. The letter then lays out the step-up dosing plan, the inpatient observation protocol, and the CRS and ICANS monitoring framework in detail (see Section: What your physician needs to provide).

The standard EDE application set follows. The treating UAE-licensed haematologist-oncologist's licence verification is filed (MOHAP, DHA, DOH, or Sharjah Health Authority depending on practice location), at consultant grade. The patient identifier is included anonymised where the EDE submission allows. Full product details: brand name Tecvayli, generic name teclistamab-cqyv, manufacturer Janssen Biotech, Inc. (a subsidiary of Johnson and Johnson), strength (30 mg/3 mL vials at 10 mg/mL and 153 mg/1.7 mL vials at 90 mg/mL), quantity per cycle, intended treatment duration. The destination dispensing facility name, licence number, and pharmacy in charge are listed, with a chain-of-custody plan explicitly referencing continuous 2 to 8 degrees Celsius cold-chain handling through customs and into the hospital pharmacy. Approval timelines for routine cases are typically 5 to 15 business days; Tecvayli's REMS-equivalent documentation may extend a first filing toward the longer end of that band.

Where Tecvayli gets dispensed in the UAE

Tecvayli is a subcutaneous biologic supplied in single-dose vials, shipped and stored refrigerated at 2 to 8 degrees Celsius, protected from light in the original carton. It must not be frozen and

must not be shaken. Once removed from refrigeration, unopened vials may be kept at room temperature (up to 30 degrees Celsius) for a limited window per the package insert. Prepared syringes for the step-up doses and the treatment doses have separate in-use stability windows and must be used within label-specified hours of preparation. Direct-to-home delivery is not the model. The medicine ships cold-chain to a UAE-licensed hospital with inpatient observation capability where the step-up dosing is administered.

The UAE institutions with adult haematology, BCMA-bispecific administration capability, and prior named-patient import experience for cell-engager biologics include Cleveland Clinic Abu Dhabi (M42 group, ASHP-accredited pharmacy services), Sheikh Khalifa Medical City and Tawam Hospital in the SEHA network (Tawam being the national oncology referral centre developed with Johns Hopkins Sidney Kimmel), American Hospital Dubai (Mayo Clinic Care Network), and the larger NMC Healthcare flagship oncology sites. The dispensing hospital must demonstrate inpatient observation capacity for 48 hours after each of the three step-up doses and after the first full treatment dose, plus the CRS and ICANS management protocol with the appropriate critical-care escalation pathway. For patients resident in the Northern Emirates without a local haematology service equipped for BCMA bispecifics, the case routes to a Dubai or Abu Dhabi tertiary centre where the treating haematologist-oncologist holds privileges.

Real cost picture for Tecvayli in the UAE

The US wholesale acquisition cost for Tecvayli 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 administration, monitoring, or inpatient observation costs associated with step-up dosing. Patients who achieve and maintain a complete response or better for a minimum of six months on the weekly schedule may transition to every-2-week (Q2W) dosing per the FDA-approved 2024 label update, which materially reduces the annual drug cost.

For named-patient orders to the UAE, the patient-facing picture has three layers: US specialty pharmacy acquisition cost from the REMS-certified channel, cold-chain international logistics (USD 800 to 1,500 per shipment to the UAE under qualified 2 to 8 degrees Celsius shippers with continuous temperature monitoring), and regulatory documentation plus Reserve Meds coordination. The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. The dispensing hospital separately incurs inpatient observation costs for the step-up doses and the first full treatment dose, which are not part of the Reserve Meds quote. Daman National Health Insurance (operator of Thiqa), GIG Gulf, Sukoon Insurance, ADNIC, and Orient Insurance assess named-patient bispecific imports case by case. Cash-pay remains the default posture for a first cycle; insurer reimbursement is filed by the patient or the hospital after the fact.

Typical timeline for Tecvayli in the UAE

End-to-end, a first Tecvayli case in the UAE typically completes in four to seven weeks before step-up dose 1. The EDE permit runs 5 to 15 business days for routine cases, with the REMS-equivalent treatment-centre documentation sometimes extending toward the longer end. Reserve Meds confirms eligibility within 24 to 48 hours of intake and aligns sourcing through the REMS-certified US specialty pharmacy in parallel with the permit application. Cold-chain international shipping is two to four business days under a validated qualified shipper with continuous temperature data logging. UAE customs clearance under the import permit at refrigerated

handling typically takes one to three business days. The hospital pharmacy performs final lot verification and chain-of-custody reconciliation on receipt, then schedules step-up dose 1 with inpatient admission for the 48-hour observation window. Maintenance dosing thereafter is weekly until disease progression or unacceptable toxicity, transitioning to Q2W for patients who achieve and maintain a complete response or better for at least six months.

What your physician needs to provide

The treating UAE-licensed haematologist-oncologist provides the clinical anchor. The clinical justification letter typically sets out the relapsed or refractory multiple myeloma diagnosis, the molecular and cytogenetic profile where relevant, and the prior-line history. For each prior agent the letter records the drug, dose, duration, response, progression event, and reason for change. The letter explicitly addresses the indication being treated (monotherapy after at least four prior lines, or the new combination indication with daratumumab and hyaluronidase-fihj after at least one prior line), the prior BCMA exposure (CAR-T, antibody-drug conjugate, or prior bispecific), and the rationale for Tecvayli at this point in the sequence.

The step-up dosing plan and the safety framework are the second anchor and are mandatory for the EDE submission. The labelled monotherapy regimen is: step-up dose 1 on day 1 at 0.06 mg/kg, step-up dose 2 on day 4 (separation 2 to 7 days) at 0.3 mg/kg, first treatment dose on day 7 (separation 2 to 7 days from step-up dose 2) at 1.5 mg/kg, and maintenance 1.5 mg/kg once weekly thereafter until disease progression or unacceptable toxicity. Pre-medications are required before each step-up dose and before the first treatment dose: a corticosteroid, an antihistamine, and an antipyretic, administered 1 to 3 hours prior. The label requires inpatient observation for 48 hours after each of the three step-up doses and after the first full treatment dose, given the risk of cytokine release syndrome and neurotoxicity.

CRS occurred in up to 72 percent of patients in the MajesTEC-1 pivotal trial (predominantly grade 1 or 2 and concentrated around the step-up doses). ICANS occurred in approximately 6 percent of patients. Infections, hypogammaglobulinemia, and neutropenia are common and require active monitoring and supportive care, including immunoglobulin replacement in selected patients. The clinical letter documents the CRS grading and tocilizumab-based management protocol, the ICANS neurologic exam schedule (at baseline, before, and after each step-up dose and through cycle 2), and the IgG monitoring and immunoglobulin replacement triggers. The patient wallet card provided under the US REMS is replicated in the UAE patient onboarding so that any UAE emergency department understands the medicine the patient is receiving.

The licence verification, the dispensing facility licence with explicit inpatient observation capability statement, and the cold-chain chain-of-custody plan complete the package. Reserve Meds supplies the chain-of-custody and CRS/ICANS reference templates so the haematologist-oncologist's time stays on clinical content.

Common questions about Tecvayli in the UAE

Does my UAE hospital need to be REMS-certified? The FDA REMS programme does not operate in the UAE. What the receiving UAE hospital needs is the operational equivalent: inpatient observation infrastructure for the step-up doses and the first full treatment dose, the CRS grading and management protocol (with tocilizumab readily available), the ICANS neurologic exam framework, and the patient wallet card system. Major UAE tertiary centres with

haematology services typically have this in place. The dispensing-facility documentation in the EDE submission states this expressly.

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Tecvayli? Each insurer assesses BCMA bispecific named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and several require pre-authorisation. Thiqa, administered by Daman for UAE nationals in Abu Dhabi, has the broadest specialty coverage. We do not promise coverage from any insurer.

Will my DHA-licensed or DOH-licensed haematologist-oncologist's letter be sufficient? Yes, at consultant grade and where the dispensing facility licence supports BCMA bispecific administration. A DHA-licensed haematologist files for a Dubai facility, a DOH-licensed haematologist for Abu Dhabi, a MOHAP-licensed haematologist for the Northern Emirates, and a Sharjah Health Authority-licensed haematologist for Sharjah.

Why Tecvayli rather than 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 centre, 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 cell therapy centre. The selection between approaches is a treating haematologist's decision.

Why Tecvayli rather than Elrexfio (elranatamab) or Talvey (talquetamab)? Elranatamab is also a BCMA by CD3 bispecific with a similar relapsed/refractory positioning. Talquetamab targets GPRC5D by CD3 and offers a non-BCMA mechanism. The choice is a clinical decision based on prior BCMA exposure, toxicity tolerance, and treating physician judgement.

Can Tecvayli be administered at home? No. The step-up dosing and the first full treatment dose require inpatient administration with 48-hour observation. Maintenance dosing thereafter is given in a qualified outpatient setting with the ability to escalate care if CRS or ICANS symptoms emerge.

What is the typical course duration? Open-ended. Treatment is given until disease progression or unacceptable toxicity. Patients who achieve a sustained complete response of at least six months may transition to Q2W dosing per the 2024 label update.

Where Reserve Meds fits in Tecvayli cases

Reserve Meds is a US-based concierge coordinator. We do not replace your haematologist-oncologist, we do not replace the Emirates Drug Establishment or your emirate-level licensing authority, we do not certify your hospital under the US REMS (which does not extend to UAE institutions in any case), and we do not provide clinical care, REMS certification, or post-administration monitoring. What we do is orchestrate the US REMS-certified specialty pharmacy sourcing under DSCSA with full serialised chain-of-custody back to Janssen, the regulatory documentation kit your physician needs (including the CRS and ICANS reference templates), qualified 2 to 8 degrees Celsius cold-chain logistics with continuous temperature monitoring, and a single named coordinator throughout the case. Reserve Meds has documented named-patient access pathways for Tecvayli in India, Saudi Arabia, the UAE, and Qatar, and inquiry-stage demand has been observed from oncology referrers in these markets. The treating physician retains clinical responsibility for step-up dosing, inpatient observation, and ongoing CRS and ICANS surveillance per the FDA label.

Next step

If your treating haematologist-oncologist has confirmed Tecvayli as the next clinical step and the dispensing hospital has confirmed BCMA bispecific administration capability, the waitlist is the first action. Reserve Meds responds within 24 to 48 hours with eligibility confirmation and a documentation kit your physician can use. Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a UAE-licensed haematologist-oncologist's clinical judgment, and a UAE hospital with inpatient observation and CRS/ICANS management capability. Reserve Meds is the coordinator, not the prescriber.

Related

- Tecvayli drug overview
- Tecvayli in Saudi Arabia
- United Arab Emirates: the EDE named-patient pathway
- All access pathways

Sources

- FDA accelerated approval, 25 October 2022; combination approval (Tec-Dara), 5 March 2026
- FDA prescribing information for Tecvayli (current label), accessdata.fda.gov
- Moreau P et al., Teclistamab in Relapsed or Refractory Multiple Myeloma, New England Journal of Medicine 2022 (MajesTEC-1)
- Tecvayli biweekly dosing approval (Janssen press release, February 2024); EMA EPAR
- Emirates Drug Establishment portal, Issue of Permit to Import Medicines for Personal Use

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

Last medically reviewed: 2026-05-12.