Tecvayli

Oman · access guide

How to access Tecvayli from Oman, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Oman patient with heavily pre-treated relapsed or refractory multiple myeloma, typically with four or more prior lines including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody, may be evaluated by their treating haematologist for Tecvayli (teclistamab). Tecvayli is FDA-approved, developed by Janssen (Johnson & Johnson), and is the first BCMA-directed bispecific T-cell engager approved for multiple myeloma. In Oman, Tecvayli is not yet broadly registered for routine hospital pharmacy dispensing, which is why your haematologist may be navigating a named-patient import pathway with you.

This guide explains the legal pathway, what your physician needs to provide, typical timelines, and where Reserve Meds fits in.

The clinical situation

Tecvayli is a humanised IgG4 bispecific antibody that engages BCMA on malignant plasma cells and CD3 on T cells, redirecting T-cell cytotoxicity to the myeloma clone. Administration is subcutaneous on a step-up dosing schedule (0.06 mg/kg, then 0.3 mg/kg, then 1.5 mg/kg) followed by weekly maintenance at 1.5 mg/kg; after sustained response, less-frequent dosing may be considered. The step-up phase requires hospitalisation for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) monitoring at a facility capable of tocilizumab administration and intensive support. Eligibility centres on prior-line history, performance status, baseline cytopenias, and infection-risk profile. Your haematologist will identify the administering tertiary centre.

Is Tecvayli legally importable into Oman?

Yes, via the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient import framework, operating with Ministry of Health tertiary-centre coordination. The named-patient mechanism permits a DGPADC-licensed physician at a qualified haematology centre to import a medicine not locally registered when (a) the medicine is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent alternative is routinely available at that centre, (c) the physician accepts clinical responsibility, and (d) chain of custody through a licensed importer is documented.

For Tecvayli specifically, the application emphasises the centre's capability to manage CRS/ICANS inpatient monitoring during step-up dosing.

How the pathway works, step by step

1. **Consultation with your treating haematologist.** Prior-line documentation, performance-status assessment, cytopenia and infection baseline.
2. **Administering-centre identification.** A qualified Oman tertiary haematology centre with CRS/ICANS monitoring capability is nominated; beds are booked for the step-up phase.
3. **DGPADC named-patient application.** Your physician files the dossier including clinical rationale, patient reference, centre capability attestation, and dosing plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Tecvayli from the manufacturer's authorised distribution chain under DSCSA.
5. **Cold-chain shipment.** Tecvayli ships with validated temperature control to the administering hospital pharmacy.
6. **Step-up admission and ongoing therapy.** The tertiary centre admits for step-up dosing, manages CRS/ICANS prophylaxis and treatment, transitions to weekly outpatient maintenance once cleared.

What documentation your physician needs

- Clinical rationale letter confirming diagnosis, prior-line sequence (≥ 4 prior lines with PI / IMiD / anti-CD38 exposure), and Tecvayli as the indicated therapy
- Verification of SCFHS medical licence
- Identification of the administering tertiary centre with CRS/ICANS monitoring attestation
- Patient identifier (anonymised reference where possible)
- Step-up and maintenance dosing plan with supportive-care protocol

Reserve Meds provides a documentation kit that bundles the DGPADC templates reviewers expect to see for BCMA-directed bispecific named-patient files.

Costs and timing

Tecvayli's US cash-pay drug-only reference cost is weight-based; for a typical 75-85 kg patient the indicative 2026 monthly maintenance cost sits in the range of roughly USD 40,000-48,000, with a higher burden during the step-up month. Inpatient step-up hospitalisation at the administering centre is a separate local cost handled by that hospital. International logistics, DGPADC documentation handling, cold-chain shipment, and concierge coordination add incremental cost. Reserve Meds issues a transparent quote at the start of intake. Indicative range.

Indicative timing for first-dose step-up admission after cohort intake opens is 7-14 days from the moment a complete DGPADC application is submitted.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

A culturally-aware note: Oman myeloma patients often travel from regional centres to Riyadh or Jeddah tertiary haematology units for step-up hospitalisation. Our coordination includes family-caregiver support during the inpatient phase and prayer-time-sensitive dosing scheduling where feasible.

Reserve Meds's role

- **Sourcing.** Through our US-licensed specialty wholesale partner under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and DGPADC review, keyed to the BCMA-bispecific rationale.
- **Logistics.** Validated cold-chain shipment to the nominated tertiary centre.
- **Concierge case lead.** A named point of contact for your family and your haematology team through step-up and maintenance cadence.

What we do not do: we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating haematologist and the administering centre.

Frequently asked

How does Tecvayli compare with Carvykti CAR-T? Both target BCMA. Tecvayli is an off-the-shelf bispecific given on a subcutaneous schedule; Carvykti is an autologous one-time CAR-T infusion. Your haematologist will select based on disease pace, prior-line pattern, and centre capability.

Where will the step-up admission happen? At a Oman tertiary haematology centre with CRS/ICANS experience, your physician nominates the site and coordinates beds.

What is the infection risk? Bispecifics targeting BCMA are associated with hypogammaglobulinaemia and opportunistic infection risk, particularly CMV and respiratory viruses; IVIG supplementation and antimicrobial prophylaxis are standard. Your team will manage.

Will insurance cover this? Cash-pay is the default for named-patient imports. Some Oman private insurers and MoH pathways consider case-by-case reimbursement; we supply documentation but do not process claims directly.

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