Talvey

Pakistan · access guide

Talvey access in Pakistan: the DRAP named-patient pathway

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

Quick orientation

Talvey (talquetamab-tgvs) is the first and only GPRC5D x CD3 bispecific T-cell engager approved for multiple myeloma. The US FDA granted accelerated approval on 9 August 2023 for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. The medicine is administered subcutaneously on a weekly or every-two-week step-up schedule, and the US supply runs through a restricted REMS specialty channel because of the labeled cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) risks. Pakistani patients reach the medicine through the Drug Regulatory Authority of Pakistan (DRAP) Special Permission framework, also known as the NOC for Personal Use Import, filed through the Online Import and Export System (OIES) portal under the Drugs Act 1976 and the DRAP Act 2012. Reserve Meds coordinates DSCSA-compliant US specialty-wholesaler sourcing through the REMS-certified channel, validated 2 to 8 degree Celsius cold-chain logistics, and the documentation kit your haematology team needs to file.

Why patients in Pakistan need Talvey through the named-patient pathway

Pakistan's haematology footprint is concentrated at a handful of institutions: Aga Khan University Hospital (AKUH) in Karachi (with the country's strongest JCI-accredited haematology service and established BMT program), Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore and Peshawar (the country's flagship cancer center with the largest myeloma cohort), the Indus Hospital and Health Network, Pakistan Kidney and Liver Institute (PKLI) Lahore, the Combined Military Hospitals (CMH) network, and Shifa International Hospital Islamabad. Multiple myeloma diagnosis and front-line treatment with proteasome inhibitors, immunomodulatory agents, and increasingly daratumumab (anti-CD38) is established practice. Autologous stem cell transplant is available at AKUH and SKMCH&RC. What is consistently missing on Pakistani formularies for the triple-class-refractory or BCMA-experienced patient is a GPRC5D bispecific antibody as a routinely stocked product.

Talvey is not currently registered with DRAP. The clinical case for reaching across the border is sequencing-driven. Talvey is positioned for patients who have progressed through triple-class therapy and, importantly, for patients who have progressed after BCMA-directed therapies. The GPRC5D target differs from BCMA and offers a distinct mechanism. Pakistani families who reach us at this point in the disease have typically been through multiple lines and need a non-BCMA bispecific. The funding pattern is most often a combination of family resources and overseas Pakistani family members in the GCC (Saudi Arabia, UAE), the UK, North America, and Australia wiring in support of the case.

The DRAP named-patient pathway for Talvey

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section, with the Drug Registration Board overseeing new product registration. For unregistered medicines required for a specific patient, DRAP issues a Special Permission, also called the No Objection Certificate (NOC) for Personal Use Import, filed through the Online Import and Export System (OIES) portal at www.dra.gov.pk. The legal foundation is the Drugs Act 1976 and the DRAP Act 2012.

For Talvey specifically, the clinical-justification angle in the DRAP filing is the prior-line documentation, the BCMA-exposure context where applicable, and the REMS-equivalent inpatient monitoring readiness. The strongest applications consistently document: a confirmed diagnosis of multiple myeloma with current ISS or Revised ISS stage, cytogenetics, and disease markers; the documented prior treatment sequence (at least four prior lines including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody) with dates, regimen, response, and reason for discontinuation; the BCMA-directed therapy history if relevant; the proposed dosing plan following one of the two FDA-labelled regimens; the premedication plan; and the planned 48-hour inpatient observation after each step-up dose and the first treatment dose, with documented CRS-response capacity and ICANS-response plan.

A complete DRAP application includes the clinical justification letter from the treating haematologist or medical oncologist with active Pakistan Medical and Dental Council (PMDC) registration, the disease-staging documentation, the prior-therapy table, the proposed dosing and monitoring plan, the destination dispensing facility license, and the chain-of-custody plan describing how the medicine will move from the US REMS-certified specialty wholesaler through the importer to the dispensing pharmacy under 2 to 8 degrees Celsius cold-chain handling. Approval timelines for routine DRAP NOC applications at major institutions run four to eight weeks; first-time bispecific-antibody imports at any given Pakistani institution can extend to ten to sixteen weeks given the limited precedent.

Where Talvey gets dispensed in Pakistan

Talvey administration in Pakistan requires a tertiary center with documented bispecific-antibody readiness: an inpatient unit able to monitor patients for 48 hours after each step-up dose and after the first full dose, on-formulary tocilizumab and corticosteroid escalation pathway, ICU access, and a haematology service experienced with CRS. The institutions that meet this profile in Pakistan are AKUH Karachi (the most consistent fit), SKMCH&RC Lahore and Peshawar (the country's flagship cancer center with the deepest haematology bench), the Indus Hospital and Health Network in Karachi, PKLI Lahore, Liaquat National Hospital Karachi, the CMH network for military families, Shifa International Hospital Islamabad, and Quaid-e-Azam International Hospital Islamabad.

The dispensing facility must hold validated 2 to 8 degree Celsius storage with continuous temperature monitoring. The chain-of-custody documentation runs from the US REMS-certified specialty wholesaler (Janssen contracts with McKesson Specialty, Cardinal Specialty, and Onco360) through the international cold-chain courier, through Pakistani customs at Karachi or Lahore international airports, into the institutional pharmacy, and finally to the inpatient bedside at the time of each step-up administration. The GPRC5D-specific clinical features (dysgeusia, nail changes, skin reactions, weight loss) are part of the pre-treatment patient education kit the institution prepares.

Real cost picture for Talvey in Pakistan

US wholesale acquisition cost (WAC) for Talvey is approximately USD 25,000 per month for the standard 0.4 mg/kg weekly subcutaneous regimen at an average adult body weight. The every-two-week 0.8 mg/kg regimen has comparable monthly drug economics. Annual WAC at weekly dosing runs approximately USD 300,000 to USD 360,000 for an 80 kg adult. At the prevailing USD/PKR rate (1 USD = approximately 280 PKR in May 2026), monthly drug cost converts to roughly PKR 7.0 million per month, or PKR 84 to 100 million per year at weekly dosing. Because the Pakistani Rupee has been volatile and inflation remains elevated, Reserve Meds quotes Talvey in USD and accepts wire transfers from any USD-accessible source.

International cold-chain logistics from US specialty wholesaler to Pakistani institutional pharmacy typically runs USD 800 to USD 2,200 per shipment depending on quantity, destination metro (Karachi, Lahore, Islamabad), and urgency. DRAP NOC application fees are nominal relative to drug cost. The Reserve Meds concierge fee is a separate transparent line item on every firm quote.

On the payer side, no Pakistani private insurer (Adamjee, EFU, Jubilee, IGI, TPL, State Life) reimburses a USD 25,000-per-month bispecific antibody as a standard line item. Federal Government Employees Health Insurance and provincial health card schemes (Sehat Sahulat Card) do not cover unregistered international biologics at this run rate. The State Bank of Pakistan's annual medical-treatment outward remittance allowance is constrained relative to monthly Talvey cost; in practice, funding flows from overseas family members directly to the institutional account in PKR-equivalent USD wires. We do not promise coverage from any insurer or scheme.

Typical timeline for Talvey in Pakistan

From the date a complete documentation set reaches Reserve Meds, the typical pattern is six to ten weeks to first dose. DRAP NOC approval for routine cases at major institutions runs four to eight weeks; first-time bispecific-antibody imports at any given Pakistani institution can extend to ten to sixteen weeks. US REMS specialty-wholesaler order placement runs in parallel with the DRAP filing once the application is complete. International cold-chain transit to Pakistan runs five to seven days door-to-door for Karachi, Lahore, or Islamabad. Customs clearance at the Pakistani port runs three to seven business days where documentation is in order. Institutional pharmacy receipt, quality verification, and scheduling of the first step-up dose runs three to five business days. The biological pacing of the step-up sequence (Day 1, Day 4, Day 7 for the weekly regimen, with the corresponding longer ramp for the every-two-week regimen) is non-negotiable.

What your physician needs to provide

For a Pakistani haematologist or medical oncologist prescribing Talvey through the DRAP pathway, the clinical justification letter is the cornerstone of the application. The letter, signed with active PMDC registration, documents the patient's myeloma diagnosis with current ISS or R-ISS stage, cytogenetic risk markers, serum free light chain ratio, M-protein trajectory, and bone marrow plasma cell percentage. The prior-therapy table covers each of the qualifying prior lines with regimen, dates, best response, duration of response, and reason for discontinuation. BCMA-directed exposure history, where applicable, is documented as a discrete element of the file.

The dosing plan follows one of the two FDA-labelled regimens (weekly 0.4 mg/kg or every-two-week 0.8 mg/kg) with the corresponding step-up sequence. Premedication, monitoring (48-hour inpatient observation after each step-up dose and after the first full treatment dose, CRS grading and tocilizumab readiness, ICANS monitoring with ICE score documentation, neutropenia and infection surveillance, hypogammaglobulinemia management with IVIG support where indicated, baseline tuberculosis screening given country epidemiology), and the GPRC5D-specific on-target effects (dysgeusia, nail changes, skin reactions, weight loss with multidisciplinary dietitian and dermatology referral pathway) are covered. Adverse event reporting through DRAP's Pharmacovigilance Cell within the Health Services Division applies and is referenced in the documentation kit; reporting obligations remain with the prescribing physician and the institution.

Common questions about Talvey in Pakistan

Is Talvey registered in Pakistan? Not at this page date. Janssen has not filed Talvey with DRAP for commercial registration. Access runs through the DRAP Special Permission / NOC for Personal Use Import pathway with US-source supply under DSCSA chain-of-custody.

Can my haematologist administer Talvey in Pakistan? Yes, at a center with documented bispecific-antibody readiness, on-formulary tocilizumab, ICU access, and an inpatient unit able to monitor 48 hours after each step-up dose. AKUH Karachi, SKMCH&RC Lahore and Peshawar, Indus Hospital, PKLI Lahore, Liaquat National, the CMH network, Shifa International, and Quaid-e-Azam International all meet this profile.

Will Adamjee, EFU, Jubilee, IGI, TPL, or State Life cover this? No Pakistani private insurer reimburses a USD 25,000-per-month bispecific antibody as a standard line item. Federal and provincial health schemes do not cover unregistered international biologics at this run rate. Cash-pay funded through family resources, often with overseas family support from the GCC, UK, North America, or Australia, is the default operating posture.

My father progressed on Carvykti six months ago. Is Talvey a sensible next step? The GPRC5D target on Talvey is distinct from the BCMA target on Carvykti, and Talvey is one of the standard sequencing options after BCMA-directed therapy progression. The clinical decision rests with the treating haematology team after current disease assessment.

What about the taste changes and weight loss? Dysgeusia is a labelled GPRC5D on-target effect occurring in the majority of patients. Weight loss frequently follows. The institution's multidisciplinary care plan typically includes a clinical dietitian referral, dose modification or dosing-interval adjustment when severe, and oral and skin care guidance. Most patients adapt with structured support; some require dose interruption.

What about tuberculosis screening? Pakistan has a meaningful tuberculosis burden, and baseline TB screening is treated as routine, not optional, before starting any biologic with potential immune effects. The treating haematologist orders chest X-ray, IGRA where available, and TB symptom review as part of the standard pre-treatment workup. This is a clinical judgement step, not a DRAP requirement, but it shows up in well-prepared applications.

How does the funding flow work in practice? Funds wire from one or more overseas family members directly to the institutional account in PKR-equivalent USD, with milestone-tagged tranches at workup acceptance, step-up admission, and ongoing weekly or every-two-week dosing. The Reserve Meds concierge fee is wired separately to Reserve Meds in the US. We do not handle drug cost wires through Reserve Meds accounts; the family pays the institution through standard channels.

Where Reserve Meds fits in Talvey cases

Reserve Meds is a US-based concierge coordinator. We do not replace your haematologist, we do not replace DRAP, and we do not replace your institutional pharmacy. For Talvey specifically, we orchestrate the US-side sourcing through a DSCSA-compliant REMS-certified specialty channel (Janssen contracts with McKesson Specialty, Cardinal Specialty, and Onco360), build the documentation kit your physician submits to DRAP through the OIES portal, coordinate validated 2 to 8 degree Celsius cold-chain logistics with continuous temperature logging into Pakistan, manage the multi-currency funding workflow with overseas family wires from the GCC, UK, North America, and Australia, and assign a single named coordinator through the case. Pediatric dosing does not apply: Talvey is adult-only.

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