Talvey

India · access guide

Talvey access in India: the CDSCO 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. Indian patients reach the medicine through the CDSCO personal-import framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI), or through institutional Compassionate Use at hospitals such as AIIMS New Delhi and Tata Memorial Centre Mumbai. 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 hematologist needs to file.

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

India's hematology and bone-marrow-transplant capability is significant and growing. Tata Memorial Centre Mumbai (with the country's largest myeloma cohort), AIIMS New Delhi, Christian Medical College (CMC) Vellore, PGIMER Chandigarh, Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis Memorial Research Institute Gurgaon, Medanta The Medicity Gurgaon, Kokilaben Mumbai, MGM Chennai, HCG Cancer Centre Bangalore, and Manipal Hospitals Bangalore run BMT and complex hematology programmes. Proteasome inhibitors (bortezomib, carfilzomib), immunomodulatory agents (lenalidomide, pomalidomide), and anti-CD38 antibodies (daratumumab) are available locally. Domestically developed CAR-T capacity (NexCAR19 and others) has grown. What is consistently missing on local formularies for the triple-class-refractory or BCMA-experienced patient is a GPRC5D bispecific antibody as a routinely stocked product.

The clinical case for reaching across the border is sequencing-driven. Talvey is positioned for patients who have progressed through triple-class therapy (PI plus IMiD plus anti-CD38) and, importantly, for patients who have progressed after BCMA-directed therapies (Carvykti, Abecma, Tecvayli, Elrexfio). The GPRC5D target differs from BCMA and offers a distinct mechanism for patients whose myeloma has already escaped BCMA pressure. Indian families who reach us at this point in the disease have typically been through multiple lines including BCMA-directed therapy and need a non-BCMA bispecific with a defined step-up schedule, subcutaneous administration, and predictable manufacturing supply.

The CDSCO Rule 36 named-patient pathway for Talvey

The legal foundation for personal import of an unregistered or non-stocked medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application; for a weekly or every-two-week subcutaneous biologic this covers a meaningful treatment runway per filing.

For institutional Compassionate Use of drugs not approved or not locally stocked, the parallel pathway is the Compassionate Use application to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. Triple-class refractory multiple myeloma fits the life-threatening condition framing. AIIMS New Delhi, Tata Memorial Centre Mumbai, and CMC Vellore have established Compassionate Use workflow for advanced hematology.

For Talvey specifically, the clinical-justification angle in the Form 12A 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), each with dates, regimen, response, and reason for discontinuation; the BCMA-directed therapy history if relevant (prior progression after Carvykti, Abecma, Tecvayli, or Elrexfio); the proposed dosing plan following one of the two FDA-labelled regimens (weekly 0.4 mg/kg subcutaneous after step-up doses of 0.01 mg/kg and 0.06 mg/kg, or every-two-week 0.8 mg/kg subcutaneous after step-up doses of 0.01 mg/kg, 0.06 mg/kg, and 0.4 mg/kg); the premedication plan (corticosteroid, antihistamine, antipyretic 1 to 3 hours prior to each step-up dose and the first treatment dose); and most critically the planned 48-hour inpatient observation after each step-up dose and after the first treatment dose, with documented CRS-response capacity (tocilizumab on hand, ICU escalation pathway) and ICANS-response plan. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where documentation is complete; first-time GPRC5D-bispecific imports at an institution that has not previously administered Talvey may run longer for institutional pharmacy and clinical-readiness verification. Practical end-to-end planning runs two to four weeks from physician decision to dispensed material because upstream documentation assembly and downstream cold-chain logistics, not the regulator's stamp, set the pace.

Where Talvey gets dispensed in India

Talvey administration in India requires a tertiary or quaternary center with documented bispecific-antibody or CAR-T-grade clinical 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 hematology service experienced with cytokine release syndrome and ICANS. The institutions that meet this profile in India most consistently are AIIMS New Delhi (NCI-designated cancer hub with comprehensive hematology and BMT), Tata Memorial Centre Mumbai (the country's flagship cancer institute with a 1,200+ patient myeloma cohort), Christian Medical College Vellore, PGIMER Chandigarh, Apollo Hospitals' flagship sites in Chennai, Delhi, Bangalore, Hyderabad, and Kolkata, Fortis Memorial Research Institute Gurgaon, Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, HCG Cancer Centre Bangalore, and Manipal Hospitals Bangalore.

The dispensing facility must hold a Drug License under Schedule M and maintain 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 under Talvey's REMS) through the international cold-chain courier, through Indian customs at the relevant CDSCO Port Office, into the institutional pharmacy, and finally to the inpatient bedside at the time of each step-up administration. Talvey also carries a distinct clinical feature relevant to dispensing: the GPRC5D target is expressed on plasma cells and on epithelial tissues including the tongue and skin, producing a labelled adverse-effect profile of dysgeusia (taste alteration), nail changes, skin reactions, and weight loss. The dispensing institution prepares the patient and family for these on-target effects as part of the pre-treatment education.

Real cost picture for Talvey in India

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 depending on patient weight. Annual WAC at weekly dosing runs approximately USD 300,000 to USD 360,000 for an 80 kg adult. At the prevailing USD/INR rate (1 USD = approximately 83 INR in May 2026), monthly drug cost converts to roughly INR 20.7 lakh per month, or INR 2.5 to 3.0 crore per year at weekly dosing.

International cold-chain logistics from US specialty wholesaler to Indian institutional pharmacy typically runs USD 600 to USD 1,800 (approximately INR 50,000 to INR 1.5 lakh) per shipment depending on quantity, destination metro, and urgency. CDSCO Form 12A 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, Indian private insurance behavior for triple-class-refractory myeloma is mixed. Star Health, HDFC ERGO, ICICI Lombard, Niva Bupa, and Tata AIG each assess GPRC5D-bispecific imports case by case; some reimburse a percentage subject to oncology sub-limits, most require pre-authorization. CGHS provides for life-saving medicines not in the standard formulary to be considered case-by-case by an Expert Committee under Special DG (DGHS), with stricter constraints for drugs not approved by CDSCO. The National Policy for Rare Diseases 2021 financial assistance ceiling is below annual Talvey cost. Many myeloma-funded Talvey courses in India are paid by a mix of insurance, the patient's family across multiple cities, and overseas relatives wiring to a designated institutional account. We do not promise coverage from any insurer or scheme.

Typical timeline for Talvey in India

From the date a complete documentation set reaches Reserve Meds, the typical pattern is two to three weeks to first dose. CDSCO Form 12A filing to Form 12B issue runs one to two business days for routine applications and a few days longer for first-time GPRC5D-bispecific imports at the institution. US REMS specialty-wholesaler order placement and pick-pack-ship typically runs three to seven business days. International cold-chain transit to India runs three to six days door-to-door for major metro destinations. Customs clearance at the CDSCO Port Office runs one to three business days where documentation is in order. Institutional pharmacy receipt, quality verification, and scheduling of the first step-up dose runs two to four business days. The biological pacing is non-negotiable: Step-up Dose 1, Step-up Dose 2 (with 2 to 4 days separation), First Treatment Dose (with 2 to 4 days separation), then weekly or every-two-week subcutaneous administration thereafter.

What your physician needs to provide

For an Indian hematologist or medical oncologist prescribing Talvey through the CDSCO Rule 36 pathway, the clinical justification letter is the cornerstone of the application. The letter, signed by a Registered Medical Practitioner holding an active National Medical Commission registration number, documents the patient's myeloma diagnosis with current ISS or R-ISS stage, cytogenetic risk markers (presence or absence of t(4;14), t(14;16), del(17p), 1q gain or amplification, TP53 mutation), 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 because GPRC5D-directed Talvey is a logical sequencing option after BCMA progression.

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 (corticosteroid, antihistamine, antipyretic 1 to 3 hours prior) is documented for each step-up dose and the first treatment dose. The monitoring plan covers the 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, and the GPRC5D-specific on-target effects (dysgeusia, nail changes, skin reactions, weight loss) with the multidisciplinary care plan (dietitian referral, dermatology consultation as needed). Pharmacovigilance reporting through the Indian Pharmacopoeia Commission's PvPI programme applies.

Common questions about Talvey in India

Is Talvey registered in India? Talvey is not currently approved by CDSCO as a registered marketed product. Access for Indian patients runs through the Rule 36 personal-import pathway or institutional Compassionate Use. The Reserve Meds documentation kit prepares both the Form 12A application and the institutional Compassionate Use letter where the institution prefers that route.

Can my hematologist administer Talvey in India? Yes, at a center with documented bispecific-antibody or CAR-T-grade readiness, on-formulary tocilizumab, ICU access, and an inpatient unit able to monitor 48 hours after each step-up and the first full dose. AIIMS, Tata Memorial, CMC Vellore, PGIMER, Apollo flagship sites, Fortis Memorial, Medanta, Kokilaben, MGM, HCG, and Manipal all meet this profile.

Will Star Health, HDFC ERGO, ICICI Lombard, Niva Bupa, or Tata AIG cover this? Each insurer assesses GPRC5D-bispecific imports case by case. Some reimburse a percentage subject to oncology sub-limits; most require pre-authorization. Reserve Meds supplies the documentation set; the claim itself sits with you or your hospital. Cash-pay is the default operating posture for cross-border named-patient supply.

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, so Talvey is one of the standard sequencing options after BCMA-directed therapy progression. The clinical decision rests with the treating hematology team after current disease assessment, but the post-BCMA setting is exactly where Talvey is positioned. Talvey versus Tecvayli versus Elrexfio in the post-BCMA setting is a clinical judgement call by the hematology team.

What about the taste changes and weight loss I have read about? Dysgeusia (taste alteration) is a labelled GPRC5D on-target effect occurring in the majority of patients, ranging from mild metallic taste to significant aversion. 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 ICANS? Immune effector cell-associated neurotoxicity syndrome is in the FDA label as a labeled risk. The Indian institutional pharmacy and clinical team monitor ICE score, hand-writing, level of consciousness, and language daily during the step-up window. ICANS is less common with bispecific antibodies than with CAR-T, but the readiness pathway (corticosteroid escalation, neurology consultation, ICU access) is the same.

Can the medicine be given in a smaller city? The step-up sequence is best done at a tertiary or quaternary center with the documented CRS and ICANS readiness above. After the step-up sequence and first treatment dose, weekly or every-two-week subcutaneous administration can be transitioned to a day-care oncology unit closer to home in coordination with the originating center.

Where Reserve Meds fits in Talvey cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist, we do not replace CDSCO, 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 for Form 12A or institutional Compassionate Use, coordinate validated 2 to 8 degree Celsius cold-chain logistics with continuous temperature logging into India, assign a single named coordinator through the case, and stay through the multi-month dosing arc including refill cadence as the patient progresses through the weekly or every-two-week schedule. 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.

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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