**Talvey**

Egypt · access guide

# Talvey access in Egypt: the EDA 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. Egyptian patients reach the medicine through the Egyptian Drug Authority (EDA) personal-import pathway under Law No. 151 of 2019 and Pharmacy Law No. 127 of 1955 as amended. 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 Egypt need Talvey through the named-patient pathway

Egypt's haematology footprint is concentrated at Cairo University's Nasser Institute, Ain Shams University Hospitals, the National Cancer Institute (NCI) Cairo University, the 57357 Children's Cancer Hospital, the Maadi Military Medical Complex, and the major private oncology platforms (Cleopatra Hospital Group, Dar Al Fouad, Saudi German Hospital Cairo, Andalusia Group). Multiple myeloma diagnosis and front-line treatment with proteasome inhibitors and immunomodulatory agents is established practice; daratumumab (anti-CD38) has reached the Egyptian formulary at major institutions, and the country's transplant capability supports autologous stem cell transplant in younger fit patients. What is consistently missing on Egyptian 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 the EDA. 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. The GPRC5D target differs from BCMA and offers a distinct mechanism. Egyptian families who reach us at this point in the disease have typically been through multiple lines and need a non-BCMA bispecific with a defined step-up schedule, subcutaneous administration, and predictable manufacturing supply. The funding pattern is most often a combination of family resources and overseas Egyptian family members in the GCC, Saudi Arabia, the United States, and Europe wiring in support of the case.

## The EDA named-patient pathway for Talvey

The legal foundation for personal import of unregistered medicines into Egypt is the Egyptian Drug Authority's framework under Law No. 151 of 2019 (which established the EDA as the unified regulatory authority) and the Pharmacy Law No. 127 of 1955 as amended. The EDA Central Administration for Pharmaceutical Affairs handles personal-import applications for unregistered medicines required for a specific named patient, filed through the institution's import pharmacy and submitted to the EDA's Drug Inspection Department.

For Talvey specifically, the clinical-justification angle in the EDA 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; the proposed dosing plan following one of the two FDA-labelled regimens (weekly 0.4 mg/kg subcutaneous after step-up doses, or every-two-week 0.8 mg/kg subcutaneous after the corresponding three-step ramp); 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 (tocilizumab on hand, ICU escalation pathway) and ICANS-response plan.

A complete EDA application includes the clinical justification letter from the treating haematologist or medical oncologist with active Egyptian Medical Syndicate registration, the disease-staging documentation, the prior-therapy table, the proposed dosing and monitoring plan, the destination dispensing facility license under Pharmacy Law No. 127 of 1955, 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 EDA personal-import cases run 3 to 6 weeks; complex first-time bispecific-antibody imports at any given Egyptian institution can extend to 8 to 10 weeks given the limited precedent.

## Where Talvey gets dispensed in Egypt

Talvey administration in Egypt 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 cytokine release syndrome. The institutions that meet this profile in Egypt are concentrated in Cairo: the National Cancer Institute (Cairo University), the Nasser Institute, Ain Shams University Hospitals, the Children's Cancer Hospital 57357 (which sees AYA myeloma cases), the Maadi Military Medical Complex, and the major private oncology platforms (Cleopatra Hospital Group with Cairo Specialized Hospital, Dar Al Fouad, Saudi German Hospital Cairo, Andalusia Group). Outside Cairo, Alexandria University's Faculty of Medicine and the Mansoura Oncology Center participate in the broader haematology referral pattern, though step-up sequence cases most often route to Cairo.

The dispensing facility must hold validated 2 to 8 degree Celsius storage with continuous temperature monitoring under Pharmacy Law No. 127 of 1955. 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 Egyptian Customs Authority clearance, 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 Egypt

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/EGP rate (approximately 1 USD = 48 EGP in May 2026, with meaningful rate volatility), monthly drug cost converts to roughly EGP 1.2 million per month at the time of this writing, with the figure highly dependent on rate movement. Because the Egyptian pound has shown significant inflation pressure and exchange-rate movement, Reserve Meds quotes Talvey in USD and accepts wire transfers from any USD-accessible source.

International cold-chain logistics from US specialty wholesaler to Egyptian institutional pharmacy typically runs USD 800 to USD 2,200 per shipment depending on quantity, destination metro (Cairo, Alexandria), and urgency. EDA personal-import 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, Egyptian payer behavior for triple-class-refractory myeloma is restrictive at the Talvey price point. The Universal Health Insurance system, the Health Insurance Organization (HIO), and the Ministry of Health Treatment at State Expense system do not reimburse the medicine as a standard line item. Private insurers (Allianz Egypt, AXA Egypt, MetLife, Bupa Egypt) assess case by case with most commercial plans falling short of meaningful coverage at this monthly run rate. The dominant funding pattern for Egyptian Talvey cases is family resources supplemented by overseas Egyptian family members in the GCC, Saudi Arabia, North America, or Europe wiring to a designated institutional account. We do not promise coverage from any insurer or scheme.

## Typical timeline for Talvey in Egypt

From the date a complete documentation set reaches Reserve Meds, the typical pattern is four to six weeks to first dose. EDA personal-import approval for routine cases runs 3 to 6 weeks; first-time bispecific-antibody imports at any given Egyptian institution can extend to 8 to 10 weeks. US REMS specialty-wholesaler order placement runs in parallel with the EDA filing once the application is complete. International cold-chain transit to Egypt runs four to seven days door-to-door. Customs clearance at the Egyptian Customs Authority runs two to five 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 an Egyptian haematologist or medical oncologist prescribing Talvey through the EDA pathway, the clinical justification letter is the cornerstone of the application. The letter, signed with active Egyptian Medical Syndicate 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), 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 the Egyptian Pharmaceutical Vigilance Center (EPVC) applies and is referenced in the documentation kit; reporting obligations remain with the prescribing physician and the institution.

## Common questions about Talvey in Egypt

**Is Talvey registered in Egypt?** Not at this page date. Janssen has not filed Talvey with the EDA for commercial registration. Access runs through the EDA personal-import pathway with US-source supply under DSCSA chain-of-custody.

**Can my haematologist administer Talvey in Egypt?** Yes, at a Cairo-area tertiary 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. NCI Cairo, Nasser Institute, Ain Shams, the Maadi Military Medical Complex, and the major private oncology platforms (Cleopatra, Dar Al Fouad, Saudi German, Andalusia) meet this profile.

**Will Allianz Egypt, AXA Egypt, MetLife, or Bupa Egypt cover this?** Each insurer assesses GPRC5D-bispecific imports case by case at this monthly run rate, with most commercial plans falling short of meaningful coverage. The Universal Health Insurance system, HIO, and the Ministry of Health Treatment at State Expense system do not reimburse the medicine as a standard line item. Cash-pay funded through family resources, often with overseas family support, 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, 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 Egyptian institutional team monitors 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 administered outside Cairo?** The step-up sequence is best done at a Cairo-area tertiary 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 Cairo center.

## 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 the EDA, 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 the EDA, coordinate validated 2 to 8 degree Celsius cold-chain logistics with continuous temperature logging into Egypt, manage the multi-currency funding workflow with overseas family wires, 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.




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