## Carvykti

Turkey · access guide

# Carvykti access in Turkey: the TITCK named-patient pathway

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

## Quick orientation

Carvykti (ciltacabtagene autoleucel) is an autologous BCMA-directed chimeric antigen receptor T-cell therapy approved by the US Food and Drug Administration in February 2022 for adults with relapsed or refractory multiple myeloma. The April 2024 label update moved the indication to the second-line setting in lenalidomide-refractory disease after one or more prior lines. The product is manufactured by Janssen Biotech and Legend Biotech. The CARTITUDE-1 pivotal trial reported a 97 percent overall response rate with 67 percent stringent complete response in heavily pretreated populations. Access for a Turkish patient runs through the Turkish Medicines and Medical Devices Agency (Turkiye Ilac ve Tibbi Cihaz Kurumu, TITCK) named-patient framework combined with autologous cell collection arranged at a CAR-T-authorised center.

## Why Turkish patients ask about Carvykti

Turkey has one of the strongest tertiary oncology and hematology infrastructures in the broader region. Hacettepe University Medical Faculty, Ankara University Cebeci Medical Faculty, Istanbul University Cerrahpasa Medical Faculty, Marmara University Pendik Training and Research Hospital, Anadolu Medical Center in collaboration with Johns Hopkins, Acibadem Healthcare Group, Memorial Healthcare Group, and the Medipol Mega University Hospital all carry deep hematology-oncology programs with active autologous stem cell transplant capacity. Several Turkish centers have stood up or are in the process of standing up CAR-T programs. Families arrive at the Carvykti question after the conventional myeloma sequence has been exhausted, and the conversation increasingly takes place against a backdrop where some CAR-T capability may be domestically available at a leading Istanbul or Ankara center.

## The TITCK named-patient pathway for Carvykti

Turkey's framework for unregistered-medicine import runs through TITCK under Regulation on Medicinal Products for Human Use. The personal-use import permit is available where a TITCK-licensed physician documents the clinical necessity of a medicine not registered in Turkey and where no clinically equivalent local alternative is suitable. For autologous CAR-T, TITCK can issue the import permit in principle, with operational complexity in infusion-center identification and cell shipment chain of custody. The Social Security Institution (SGK) reimbursement for CAR-T is a separate question handled case by case where Carvykti is on the SUT (Health Implementation Communique) list. The SGK posture for cross-border CAR-T is generally not aligned with cash-pay-only assumption, and Reserve Meds is positioned to support either route.

A complete TITCK application includes the clinical justification letter from the treating hematologist, the physician's TITCK license verification, the destination infusion center identification with FACT or equivalent CAR-T accreditation, the leukapheresis collection plan, the Janssen manufacturing slot reservation, and the post-infusion monitoring plan. TITCK processing for routine personal-use cases is typically 5 to 20 business days; CAR-T cases sit in an 8-to-16-week operational envelope.

## Where Carvykti cases are infused for Turkish patients

The realistic infusion-center options for Turkish patients are a domestic Turkish CAR-T center where capability has been stood up (Istanbul or Ankara academic medical centers), a US academic medical center (MD Anderson, Memorial Sloan Kettering, Dana-Farber, City of Hope, Moffitt), or a European reference center. Visa access to the US and EU for Turkish nationals is established. Leukapheresis collection can be performed in Turkey at a qualified academic apheresis center under chain-of-custody arrangements, with the apheresis product shipped to the Janssen manufacturing facility.

## Real cost picture for Carvykti cases

US wholesale acquisition cost for Carvykti is approximately USD 465,000 per dose. The all-in clinical envelope for an international BCMA CAR-T case runs USD 650,000 to USD 950,000. The Turkish lira trades at approximately 35 to 40 TRY to 1 USD with significant volatility, so the drug acquisition cost converts to approximately TRY 16.3 million to TRY 18.6 million at current rates. The all-in envelope sits in the TRY 22.7 million to TRY 38 million band. Where the case proceeds through SGK reimbursement at a Turkish CAR-T center, the cost profile shifts substantially; we coordinate documentation either way. Cash-pay families work with explicit cost transparency from first contact.

## Typical timeline for Carvykti in Turkey

End-to-end, a Turkish Carvykti case typically runs 12 to 20 weeks from first physician contact to infusion-center discharge: clinical eligibility and infusion-center identification (weeks 1 to 3); TITCK documentation and travel logistics if international (weeks 3 to 6); leukapheresis collection and shipment (weeks 6 to 7); Janssen manufacturing window (weeks 7 to 12); patient travel and lymphodepleting chemotherapy (week 12 to 13); CAR-T infusion and post-infusion monitoring (weeks 13 to 16); discharge and handoff (weeks 16 to 20). Manufacturing-failure rate of approximately 5 to 10 percent is a real operational risk.

## What your physician needs to provide

For a Turkish hematologist coordinating a Carvykti case, the clinical justification letter documents the multiple myeloma diagnosis with cytogenetic and FISH risk stratification, the prior line-of-therapy summary showing exposure and refractoriness to immunomodulator, proteasome inhibitor, and anti-CD38 classes, current disease burden, performance status, comorbidity profile, fitness for lymphodepleting chemotherapy, cardiac and pulmonary baseline, and bridging therapy plan. The physician's TITCK license number and institutional affiliation complete the paperwork.

## Common questions about Carvykti in Turkey

**Is the TITCK pathway open for CAR-T?** Yes in principle. The operational gate is infusion-center capability.

**Can a Turkish center handle the full case in-country?** Some Istanbul and Ankara academic centers have stood up or are standing up CAR-T programs. The Reserve Meds clinical

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