

## Carvykti

Jordan · access guide

# Carvykti access in Jordan: the JFDA named-patient pathway

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

## Quick orientation

Carvykti (ciltacabtagene autoleucel) is a BCMA-directed autologous CAR-T cell therapy developed by Janssen (Johnson & Johnson) and Legend Biotech. It is approved by the US FDA for relapsed or refractory multiple myeloma after 1+ prior lines including PI and IMiD (CARTITUDE-4, lenalidomide-refractory). The standard regimen is single infusion  $0.75 \times 10^6$  CAR-positive viable T cells per kg after lymphodepletion with fludarabine 30 mg/m<sup>2</sup> and cyclophosphamide 300 mg/m<sup>2</sup> x 3 days. Carvykti is available in the global pharmaceutical supply chain in single infusion bag. The drug may or may not be locally registered in Jordan, and even when registered, a Jordan family asking for Carvykti is often asking for a precise version of it (specific indication, specific presentation, specific schedule) that the local market has not caught up to. Reserve Meds coordinates the US-side sourcing, the validated cold-chain logistics, and the documentation packet your physician needs.

## Why Jordan patients need Carvykti through the named-patient pathway

The Jordan Food and Drug Administration (JFDA) administers the unregistered-medicine personal-import pathway. A Jordan Medical Association-licensed physician working at a JFDA-licensed facility files for the import permit when the medicine is approved by a recognised reference regulator (US FDA, EMA, MHRA, PMDA, or Health Canada) and a clinically suitable Jordan-registered alternative is not available. Jordan's regulatory framework is among the most developed in the Levant.

Several patterns drive these cases: indication lag against the FDA label; specialty biologic and oncology cases where local stock is constrained; payer denials in private cover; and patient-driven cross-border supply for the precise FDA-labeled originator product. For Carvykti specifically, the named-patient pathway exists to handle exactly the situations the local registered route cannot: a newer FDA indication that has not yet propagated to Jordan labeling, a presentation or strength the local agent does not reliably carry, a payer denial that is uneconomic to appeal, or a biomarker-defined regimen where the prescriber's clinical judgement runs ahead of the local label's molecular language. In each pattern, the named-patient pathway is the mechanism that connects a Jordan-licensed physician's clinical decision with US-sourced, FDA-labeled Carvykti for a specific patient.

Carvykti (FDA February 2022 for 4+ prior lines; CARTITUDE-4 expansion April 2024 to 1+ prior lines including PI, IMiD, lenalidomide refractory) is the BCMA CAR-T with the deepest response data in the BCMA CAR-T class. The earlier-line label expansion is operationally significant. Qualified treatment centres are limited.

## **The JFDA named-patient pathway for Carvykti**

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A complete application typically includes a clinical justification letter from the treating physician (diagnosis, severity or stage, prior therapies, biomarker results where relevant, why Carvykti is appropriate, why the locally available alternative is not suitable for this case); the treating physician's Jordan license verification (issued by Jordan Medical Association (JMA) and Ministry of Health); an anonymised patient identifier where the regulator submission allows; full product details (brand name Carvykti, generic ciltacabtagene autoleucel, manufacturer Janssen (Johnson & Johnson) and Legend Biotech, strength single infusion bag, quantity requested calibrated to the planned cycles or treatment duration); the destination dispensing facility name, license number, and pharmacy in charge; and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy, including cold-chain handling at 2 to 8 degrees Celsius from the US manufacturer through to the dispensing pharmacy.

For Carvykti, the clinical justification typically rests on documentation of BCMA expression; CRS, ICANS, prolonged cytopenia, secondary malignancy monitoring where applicable, line of therapy and prior treatments, and a clear statement of why this medicine is the appropriate next step in this patient's care.

Approval timelines for routine cases are typically 10 to 25 business days from a complete filing. Complex cases (rare indication, paediatric application, larger multi-cycle quantities, gene therapy or cell therapy logistics, first-import scrutiny on a presentation new to the local route) can extend to 4 to 8 weeks. The JFDA retains discretion on timing, and we do not promise specific durations.

## **Where Carvykti gets dispensed in Jordan**

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A small group of Jordan institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. For autologous cell therapy and gene therapy, the dispensing centre must hold the manufacturer's qualified-treatment-centre certification and operate the full apheresis, lymphodepletion, infusion, and post-infusion monitoring infrastructure. Tertiary and major private hospitals that fit this profile include King Hussein Cancer Center in Amman (JCI-accredited regional cancer referral), Jordan University Hospital, Al-Bashir Hospital, King Hussein Medical Center, Specialty Hospital, Istishari Hospital, Arab Medical Center, Khalidi Medical Center, Jordan Hospital, and the larger private hospitals in Amman.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a Amman-based specialty importer that holds a pharmaceutical establishment license and files the JFDA application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's pharmacy under chain-of-custody documentation, where the patient receives the infusion under specialised oncology nursing supervision with full CRS and ICANS monitoring readiness.

## Real cost picture for Carvykti in Jordan

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US WAC for Carvykti is approximately USD 465,000 single infusion, which translates to total cost of care USD 750,000 to USD 1.5M. The Jordanian dinar is pegged to the US dollar at approximately 0.71 JOD to 1 USD, so the annual reference range converts accordingly when expressed in JOD at US WAC equivalents.

International validated cold-chain logistics typically run USD 450 to USD 1,600 (approximately JOD 320 to JOD 1,140) per shipment depending on destination city, urgency, and pack size. Jordan customs and JFDA permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, each Jordan insurer assesses named-patient imports case by case. Local payer cover is administered through Jordan Insurance Company, Arab Orient Insurance, MetLife Jordan, Bupa Arabia (regional cover), and Royal Medical Services for the armed forces and dependents. We do not promise coverage from any insurer. The US manufacturer copay programmes and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage where it applies.

## Clinical evidence behind Carvykti

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Carvykti's pivotal CARTITUDE-1 (heavily pretreated myeloma, ORR >97% with deep complete responses) and CARTITUDE-4 (earlier-line expansion, lenalidomide-refractory) anchor the BCMA CAR-T class. The class-relevant Parkinsonism, Guillain-Barre syndrome, and FDA T-cell-malignancy warning (January 2024) are operationally significant.

## Typical timeline for Carvykti in Jordan

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JFDA routine processing is typically 10 to 25 business days from a complete filing. For Carvykti specifically, cold-chain shipment adds 2 to 3 days versus an ambient small molecule because validated thermal packaging, continuous temperature monitoring, and customs clearance scheduled to avoid extreme-heat exposure are non-negotiable. End-to-end, most cases complete within 3 to 6 weeks from first complete documentation to dispensing or first dose. For longer treatment courses, we coordinate cycle-by-cycle or quarterly resupply so the patient never approaches an empty pharmacy shelf.

## What your physician needs to provide

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For a Jordan-licensed physician prescribing Carvykti through the JFDA pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis with relevant staging or severity language for the indication, the prior therapy history, the rationale for Carvykti as the appropriate next step, and the precise FDA-labeled regimen (dose, route, frequency, expected duration). For Carvykti specifically, the FDA-approved regimen is single infusion  $0.75 \times 10^6$  CAR-positive viable T cells per kg after lymphodepletion with fludarabine 30 mg/m<sup>2</sup> and cyclophosphamide 300 mg/m<sup>2</sup> x 3 days.

For Carvykti, the relevant molecular or laboratory documentation includes BCMA expression; CRS, ICANS, prolonged cytopenia, secondary malignancy monitoring. The letter references the test results that establish the patient's eligibility for the FDA-labeled indication. The treating physician's Jordan license number, the dispensing facility license number, and the pharmacy in charge complete the package. Monitoring requirements relevant to Carvykti (baseline labs, imaging cadence, adverse-event surveillance) are stated in the letter and operationalised by the prescribing physician's team.

**Monitoring for Carvykti:** Apheresis day, lymphodepletion days, infusion day, daily CRS/ICANS monitoring through day 14, parkinsonism and Guillain-Barre syndrome surveillance (distinctive class signal), prolonged cytopenia surveillance, secondary malignancy long-term surveillance. **Adverse-event profile:** CRS, ICANS, prolonged cytopenias, infections, hypogammaglobulinaemia, parkinsonism and other movement disorders (distinctive class signal in BCMA CAR-T), Guillain-Barre syndrome, secondary T-cell malignancies (FDA class warning January 2024). REMS programme certification mandatory.

## Common questions about Carvykti in Jordan

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**Will my insurer cover this?** Each Jordan insurer (Jordan Insurance Company, Arab Orient Insurance, MetLife Jordan, Bupa Arabia (regional cover), and Royal Medical Services for the armed forces and dependents) assesses named-patient imports case by case. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

**Is Carvykti already locally registered in Jordan?** Local registration status can shift over time; Carvykti may already be on the Jordan register for some indications but not others, or the registered presentation may not match what the prescriber needs. The JFDA pathway exists precisely to bridge these gaps and is the cleanest legal route when the local supply chain does not match the prescription.

**What about competitors?** Alternatives in the same therapeutic class include Abecma (idecabtagene vicleucel), teclistamab, elranatamab, talquetamab, selinexor combinations. Choice depends on the patient's full profile, prior therapy, biomarker status, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed.

**How does the cold chain work?** This medicine requires cold-chain handling at 2 to 8 degrees Celsius from manufacture through to dispensing. Reserve Meds uses validated thermal packaging with continuous temperature logging. Customs clearance is scheduled to avoid prolonged tarmac exposure. The cold chain is broken only at the dispensing pharmacy.

**Will my US manufacturer assistance program help?** US patient assistance programs (PAP), copay cards, and bridge programs from Merck, Pfizer, AstraZeneca, Lilly, Roche, Genentech, Novartis, AbbVie, Janssen, Gilead, Biogen, BMS, and other manufacturers are generally restricted to US residents with US prescriptions filled at US pharmacies. Cross-border patients pay cash or use local payer cover.

**What if treatment is multi-year?** For long-running treatment, we coordinate cycle-by-cycle or quarterly resupply through the same JFDA pathway, with each shipment authorised against the same physician documentation set updated for the current cycle. Patients never need to navigate the supply chain themselves.

**Where is the medicine actually administered?** Autologous cell therapy and gene therapy infusions are administered at certified qualified treatment centres only. The patient typically commits to a 4-week local stay following infusion for adverse-event monitoring. Home administration is not appropriate for this product.

**What if my physician is at a smaller clinic that does not import directly?** The standard pattern is to route through a Amman-based specialty importer that holds a pharmaceutical establishment license. The importer files the JFDA application on behalf of the prescribing physician, takes delivery of the medicine, and transfers it under chain-of-custody to the prescribing facility's pharmacy.

## Operational notes for the JFDA workflow

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Operationally, the JFDA personal-import workflow is concentrated at King Hussein Cancer Center, Jordan University Hospital, and the larger Amman private hospitals. The Jordan Medical Association license verification, hospital pharmacy license, and the chain-of-custody plan are the core attachments. Jordan's regulatory infrastructure is among the most developed in the Levant, which often produces shorter turnaround than other regional markets for routine cases.

## Where Reserve Meds fits in Carvykti cases

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Reserve Meds is a US-based concierge coordinator. We do not replace your prescribing physician, we do not replace the JFDA, and we do not replace your dispensing pharmacy. For Carvykti specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated cold-chain logistics with appropriate temperature monitoring into Jordan, plan cycle-by-cycle resupply across longer treatment courses, and assign a single named coordinator through the case. Standard NPP coordination under our cell and gene therapy playbook applies.

### *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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### **Reserve Meds**

*reserved for you.*

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

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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