

## Carvykti

Bahrain · access guide

# How to access Carvykti for relapsed or refractory multiple myeloma from Bahrain: 2026 pathway via certified adult cell therapy centres

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Bahrain does not yet have an in-country certified cell therapy centre administering commercial BCMA-directed CAR-T. The kingdom's adult haematology infrastructure handles myeloma diagnosis, induction, salvage chemotherapy, and long-term follow-up at Salmaniya Medical Complex, King Hamad University Hospital, and Bahrain Specialist Hospital, but commercial Carvykti administration for a Bahraini-resident adult is a cross-border pathway. The closest certified options are KFSHRC Riyadh (deepest adult CAR-T programme in the Gulf, with operational depth in BCMA CAR-T), Abu Dhabi certified centres (Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, Burjeel Medical City, ADSCC, Yas Clinic), NCCCR Doha at Hamad Medical Corporation, and KHCC Amman. Carvykti registration with the National Health Regulatory Authority is verified at intake; named-patient pathway is the operational fallback if registration is not yet active. Janssen Cell Therapy Operations is the global supply partner. For a Bahraini-resident adult with relapsed or refractory multiple myeloma after at least one prior line including a PI and an IMiD and refractory to lenalidomide, the operational question is which cross-border certified centre fits the case, what the funding mechanism looks like, and what total cost of care looks like once apheresis, manufacturing wait, bridging, lymphodepletion, infusion, the post-infusion restricted-region month, and the extended six-month neurological monitoring are added together.

This page explains how the pathway works in 2026 for a Bahraini-resident adult: who qualifies, where the workup happens, where the cells are collected and infused, what the timeline looks like, what the realistic cost band is, and what to expect from the four-week post-infusion restricted-region requirement plus the extended six-month neurological monitoring that distinguishes Carvykti operationally from Abecma.

## Why Carvykti, and why now

Carvykti is ciltacabtagene autoleucel (cilta-cel), a one-time autologous BCMA-directed CAR T-cell therapy developed by Legend Biotech in partnership with Janssen. FDA February 2022 approval covered adults with relapsed or refractory multiple myeloma after four or more prior lines. The April 2024 expansion shifted the label to adults with at least one prior line including a PI and an IMiD and refractoriness to lenalidomide. CARTITUDE-4 underpinned the expansion: 74 percent reduction in the risk of disease progression or death, overall response rate 84.6 percent versus 67.3 percent.

For a Bahraini patient who has cycled through bortezomib-anchored induction and one further line, the conversation about BCMA CAR-T is now an earlier decision rather than a fourth-line salvage. Carvykti and Abecma are the two FDA-approved BCMA-directed CAR-T cell therapies. Reserve Meds does not promote one BCMA CAR-T over another. The selection is a clinical conversation between the patient and the treating haematologist.

## **What Carvykti is, in plain language**

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The patient's T cells are apheresed, shipped to manufacturing, transduced with a lentiviral vector that recognises BCMA via a distinctive dual-epitope binder, expanded over four to six weeks, and reinfused as a single intravenous dose of 0.5 to 1.0 times 10 to the sixth CAR-positive T cells per kilogram. Three days of fludarabine and cyclophosphamide lymphodepletion precede the infusion. Inpatient monitoring for CRS and ICANS runs seven to fourteen days. The patient and caregiver stay within two hours of the treating centre for four weeks for REMS-mandated monitoring, and the centre extends neurological and movement-disorder surveillance through six months.

For a Bahraini family this means the whole operational window happens at the cross-border certified centre. The treating Bahraini haematologist coordinates the workup, agrees the bridging plan, and resumes long-term follow-up once the patient returns to Bahrain after the post-infusion restricted-region requirement is complete.

## **Eligibility at a Bahraini haematologist clinic**

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For Bahraini-resident patients, the cross-border certified-centre criteria mirror the FDA label:

1. Confirmed relapsed or refractory multiple myeloma after at least one prior line including a PI and an IMiD, with refractoriness to lenalidomide.
2. Age 18 or older.
3. ECOG performance status 0 to 1; ECOG 2 reviewed case by case.
4. Adequate left ventricular ejection fraction, typically 45 percent or greater.
5. Adequate pulmonary function for fludarabine-cyclophosphamide and a potential CRS event.
6. Adequate hepatic, renal, and bone marrow reserve.
7. No active CNS myeloma.
8. No active autoimmune neurological disorder.
9. Medication reconciliation and DDI review.
10. Driving restriction during the four-week post-infusion REMS-restricted region and during the extended movement-disorder monitoring window.
11. Bridging therapy plan agreed with the treating haematologist.
12. Caregiver commitment for the four-week post-infusion restricted-region period at the cross-border centre.

The diagnostic workup pack includes SPEP and UPEP with immunofixation, serum free light chain assay, marrow biopsy and aspirate with cytogenetics including FISH for high-risk markers, skeletal survey or whole-body MRI, PET-CT, beta-2-microglobulin, albumin, and treatment history with response durations.

## **The Bahraini prescribing and supply picture, plainly**

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The National Health Regulatory Authority is the Bahraini regulator. Carvykti registration is verified at intake; if registration is not yet active the named-patient pathway runs through NHRA. Janssen Cell Therapy Operations is the global supply partner. The practical Bahraini pathway is cross-border to KFSHRC Riyadh (the regional reference for BCMA CAR-T depth), Abu Dhabi certified centres, NCCCR Doha, or KHCC Amman, with the choice driven by manufacturing-slot availability, family logistics, and funding mechanism. NHRA cross-border treatment funding for Bahraini nationals is available on a case-by-case basis. The REMS-equivalent protocol at the receiving cross-border centre mirrors the FDA framework.

## Cost band and insurance positioning

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US list price for Carvykti is approximately USD 525,000 for the product alone. Real-world total cost of care commonly runs USD 750,000 to USD 1.3 million. At 2026 indicative cross rates the BHD-equivalent total cost of care band is approximately BHD 283,000 to 490,000. Cross-border travel, accommodation for the patient and caregiver during the manufacturing wait and post-infusion restricted-region month, and ancillary costs at the receiving centre are added on top of the cell therapy line.

## What to expect on the Carvykti pathway, week by week

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Week 0 to 2: Reserve Meds builds the document pack with the Bahraini treating haematologist's office and submits first-review requests to one or two cross-border certified centres in parallel.

Week 2 to 4: Certified-centre cell therapy committee reviews. If accepted, manufacturing slot opens with Janssen; apheresis is scheduled at the cross-border centre; cross-border funding and travel logistics run in parallel.

Week 4 to 5: Cross-border transfer for apheresis. Cells ship to Janssen.

Week 5 to 10: Manufacturing wait. Bridging therapy under the Bahraini treating haematologist's direction; some bridging may happen at the cross-border centre.

Week 10: Three days of fludarabine and cyclophosphamide lymphodepletion at the cross-border centre.

Week 10 to 11: Single inpatient Carvykti infusion at the cross-border certified centre.

Week 11 to 12: Inpatient monitoring for CRS and ICANS.

Week 12 to 15: Four-week post-infusion REMS-restricted region at the cross-border centre. Reserve Meds organises proximity accommodation for patient and caregiver.

Month 4 onwards: Return to Bahrain for outpatient follow-up. Distinctive Carvykti axis: extended neurological and movement-disorder surveillance through six months, coordinated between the Bahraini treating haematologist and the cross-border certified centre.

## When Carvykti is the wrong drug

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For a Bahraini patient where disease tempo is too rapid for the manufacturing wait, where performance status has degraded below ECOG 2, where active CNS myeloma has emerged, where organ function is inadequate, where an active autoimmune neurological disorder is present, or where the patient or family cannot complete the four-week post-infusion restricted-region requirement at a cross-border centre plus the extended six-month neurological monitoring, the operational alternative is a BCMA bispecific (Tecvayli, Elrexfio) which can be initiated in Bahrain at a regional centre with step-up admission, or the GPRC5D bispecific Talvey when BCMA exposure has already happened. The other BCMA CAR-T, Abecma, is the comparable cell therapy option.

Reserve Meds does not promote one BCMA CAR-T over another. If the conversation points toward Abecma, a bispecific, or a non-cell-therapy regimen, we coordinate that pathway instead.

## What Reserve Meds does on this case

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We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Bahraini Carvykti case we build the document pack, submit first-review requests to one or two cross-border certified centres in parallel, run NHRA cross-border treatment funding and commercial cover conversations in parallel, coordinate the cross-border logistics during the manufacturing window, organise proximity accommodation and caregiver logistics for the four-week post-infusion period, and stay with the case through the extended six-month neurological monitoring window and one-year follow-up. Clinical decisions remain with your treating haematologist and the certified cell therapy programme.

### *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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