

## Abecma

Saudi Arabia · access guide

# How to access Abecma for relapsed or refractory multiple myeloma from Saudi Arabia: 2026 pathway via KFSHRC Riyadh or cross-border

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

King Faisal Specialist Hospital and Research Centre in Riyadh runs the deepest adult cell therapy and bone marrow transplant programme in Saudi Arabia, with decades of BMT experience and an active CAR-T development programme. In October 2024, KFSHRC announced that its in-house point-of-care anti-CD19 CAR-T manufacturing had reduced therapy cost by approximately 80 percent compared with commercial CAR-T pricing, with a stated goal of expanding annual gene therapy production capacity. While that initiative concerns academic CAR-T products rather than commercial Abecma directly, it signals the operational reality: KSA has the BMT and cellular therapy infrastructure to administer BCMA CAR-T at depth, and the regulatory framework (SFDA Gene Therapy Products Registration Guidelines 2023) governs the registration pathway for products such as Abecma. King Abdulaziz Medical City under National Guard Health Affairs runs parallel adult haematology and BMT programmes in Riyadh and Jeddah. For a Saudi-resident adult with triple-class-exposed relapsed or refractory multiple myeloma in 2026, the operational question is which certified centre, what the SFDA-registered Abecma access pathway looks like today, and how cross-border options to UAE or Jordan fit when in-country timing does not align.

This page explains how the pathway works in 2026 for a KSA-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 in SAR, and what to expect from the four-week REMS-restricted period after infusion.

## Why Abecma, and why now

Abecma is idecabtagene vicleucel, a one-time autologous BCMA-directed CAR T-cell therapy developed by Bristol Myers Squibb in partnership with 2seventy bio. It was the first cell therapy approved anywhere for multiple myeloma, reaching the US market in March 2021. In 2024 the FDA expanded the label to adults with two or more prior lines of therapy including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody. That expansion rested on the KarMMa-3 randomised Phase 3 trial in 386 triple-class-exposed patients, where median progression-free survival on Abecma was 13.3 months versus 4.4 months for standard of care, with overall response rate 71 percent versus 42 percent.

For a Saudi patient who has cycled through bortezomib-thalidomide-dexamethasone induction, daratumumab-anchored regimens, possibly autologous stem-cell transplant at KFSHRC or KAMC, and a carfilzomib-based salvage, the BCMA CAR-T conversation is now a realistic earlier-line option rather than a fifth-line salvage. Reserve Meds documents the operational pathway underneath that clinical conversation. The conversation itself remains with the treating haematologist.

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

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A small volume of the patient's own blood is collected by apheresis at the certified centre. The T cells from that collection are sent to BMS's manufacturing facility, where they are transduced with a lentiviral vector that teaches them to recognise BCMA, a protein expressed almost exclusively on plasma cells and myeloma cells. The engineered T cells expand to therapeutic dose over four to five weeks. While manufacturing happens, the patient continues bridging therapy to control disease burden. When the product is ready, the patient receives three days of fludarabine plus cyclophosphamide lymphodepletion, then a single intravenous infusion of the manufactured Abecma. Inpatient monitoring for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) typically runs seven to fourteen days. The patient and a caregiver then stay within two hours of the treating centre for four weeks under the FDA-mandated REMS programme.

## **Eligibility at a KSA haematologist's clinic**

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For Saudi-resident patients, the certified haematology programmes apply the FDA and EMA criteria with local adaptation:

1. Confirmed relapsed or refractory multiple myeloma after two or more prior lines including an IMiD, a PI, and an anti-CD38 monoclonal antibody.
2. ECOG performance status 0 to 1; ECOG 2 reviewed case by case.
3. Adequate left ventricular ejection fraction, typically 45 percent or greater.
4. Adequate pulmonary, hepatic, renal, and bone marrow reserve.
5. No active CNS involvement of myeloma.
6. No active infection requiring systemic therapy.
7. A bridging therapy plan agreed with the treating haematologist for the manufacturing window.
8. A caregiver commitment for the four-week REMS-restricted period after infusion.

A KSA patient should arrive at the cell therapy referral conversation with the most recent diagnostic workup: serum and urine protein electrophoresis with immunofixation, serum free light chain assay, bone marrow biopsy and aspirate with cytogenetics including FISH for high-risk markers (del17p, t(4;14), t(14;16), gain 1q), skeletal survey or whole-body MRI, PET-CT, beta-2-microglobulin, albumin, and a current treatment history with response durations. Reserve Meds organises this pack so the certified centre can give a yes or no eligibility opinion on first review.

## **The KSA administration picture, plainly**

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The relevant Saudi cell therapy infrastructure in 2026 includes:

- King Faisal Specialist Hospital and Research Centre (KFSHRC), Riyadh: the longest-established BMT and cellular therapy programme in the Kingdom, with an active CAR-T development pipeline including the in-house anti-CD19 manufacturing programme announced in late 2024. Commercial Abecma administration capability is the question to confirm at intake; the underlying BMT, ICU, supportive-care, and CRS-management infrastructure is mature. - King Faisal Specialist Hospital and Research Centre, Jeddah: the western-region sister site. - King Abdulaziz Medical City (KAMC), Riyadh and Jeddah: National Guard Health Affairs adult haematology and BMT programmes. - King Faisal Cancer Centre, Riyadh: oncology partner site.

For Saudi-resident adults where the in-country Abecma authorisation timing does not align with disease tempo, the cross-border alternatives include Cleveland Clinic Abu Dhabi or Sheikh Shakhbout Medical City in UAE (evolving CAR-T programme alignment for commercial BCMA products), King Hussein Cancer Center in Amman (the largest dedicated cancer centre in MENA, accredited for adult cell therapy), and select European or US certified centres for patients with international medical coverage.

## **The 2026 pathway, step by step**

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Week 0 to 2: Reserve Meds builds the document pack with the treating haematologist's office. We collect the most recent imaging, marrow biopsy, cytogenetics, treatment history, and laboratory panels. We submit a first-review request to one or two certified centres in parallel.

Week 2 to 4: The certified centre's cell therapy committee reviews the case. If accepted, the centre opens a manufacturing slot with BMS and schedules apheresis. The financial pre-authorisation conversation starts in parallel; for Saudi nationals, MoH or military hospital cover may apply depending on referral; commercial cover varies.

Week 4 to 5: Apheresis at the certified centre. One to two outpatient sessions. The collected T cells are shipped to BMS for manufacturing.

Week 5 to 9: Manufacturing wait. Patient continues bridging therapy under the treating haematologist's direction.

Week 9: Lymphodepletion. Three days of fludarabine plus cyclophosphamide.

Week 9 to 10: Single inpatient Abecma infusion. Day 0 of the cell therapy clock.

Week 10 to 11: Inpatient monitoring for CRS and ICANS. Tocilizumab and corticosteroids per protocol.

Week 11 to 14: REMS-restricted four-week post-infusion period. Patient and caregiver stay within two hours of the treating centre.

Month 4 onwards: Outpatient follow-up. Monthly for the first year; then quarterly. Long-term haematology surveillance for cytopenias, infections, hypogammaglobulinaemia, and second-primary malignancies.

## **Cost expectation in SAR**

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US list price for the Abecma product itself is USD 419,500 (some 2024 wholesale acquisition cost references quote USD 498,410; confirm at intake for any commercial contract). Real-world total cost of care including apheresis, bridging therapy, lymphodepletion, inpatient infusion and monitoring, CRS or ICANS management, and one-year follow-up commonly runs USD 700,000 to USD 1.0 million in US data. At 2026 indicative cross rates the SAR-equivalent product price is approximately SAR 1.57 million and the total cost of care band is approximately SAR 2.6 to 3.75 million. The KFSHRC in-house anti-CD19 cost reduction announced in 2024 applies to academic CAR-T products, not commercial Abecma; the commercial product price is set by BMS globally.

For Saudi nationals treated at MoH or military hospitals, in-country cover for SFDA-registered advanced therapies has historically extended on a case-by-case basis. The pre-authorisation conversation needs to start before apheresis, not after infusion. Commercial cover (Bupa Arabia, MedGulf, Tawuniya, others) varies in cell therapy coverage; the financial pre-authorisation review at the certified centre is the gating step.

## **Religious, ethical, and family-logistics framing**

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Cell-based therapy sits within the Islamic jurisprudential framework that already permits blood transfusion, organ transplantation, and assisted reproduction with appropriate safeguards. Abecma is the patient's own T cells engineered ex vivo and re-infused; there is no donor element, no foreign genetic material in the broad sense (the lentiviral vector is a research tool used during manufacturing, not a permanent germline modification), and the cells return to a patient whose marrow and immune system remain their own. The dominant ethical frame in Saudi Islamic medical ethics for this kind of therapy has been permissive, with the standard expectation that the family makes the treatment decision in consultation with the treating physician and according to the patient's own informed wish. The Saudi National Bioethics Committee and the SFDA Gene Therapy Products Registration Guidelines provide the regulatory context for advanced therapies.

The family-logistics burden of the four-week REMS-restricted post-infusion period is the practical pressure point. For Riyadh or Jeddah-resident patients treated in-country, logistics are simpler; for patients from Eastern Province, Hijaz, or the South travelling to KFSHRC Riyadh, the four-week stay in proximity to the treating centre requires deliberate planning. A caregiver must be present continuously; many Saudi families build a rotating caregiver schedule across two or three relatives. Reserve Meds documents the proximity-accommodation, transport, and pharmacy logistics in advance.

## When Abecma is not the right call

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For a Saudi patient where disease tempo is too rapid to accommodate the four to five week manufacturing wait, where performance status has degraded below ECOG 2, where active CNS involvement has emerged, or where caregiver availability for the post-infusion month cannot be arranged, the operational alternative is a BCMA-directed bispecific T-cell engager such as Tecvayli (teclistamab) or Elrexio (elranatamab), which are off-the-shelf, require step-up admission rather than apheresis, and have no manufacturing wait. Talvey (talquetamab) targets GPRC5D rather than BCMA and is the alternative bispecific when BCMA exposure has already happened. The other commercial BCMA CAR-T product, Carvykti (ciltacabtagene autoleucel), is also accessible in select certified centres internationally; comparative eligibility is a clinical conversation.

Reserve Meds does not push a default. The page above describes the Abecma pathway because Abecma is the BCMA CAR-T the patient has asked about. If the conversation with the treating haematologist points toward a bispecific or a different cell therapy, the operational pathway shifts accordingly.

## 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 Saudi Abecma case we build the document pack, submit first-review requests to one or two certified centres in parallel, run the financial pre-authorisation conversation alongside the clinical pre-authorisation conversation, coordinate the bridging-therapy logistics during the manufacturing window, organise the proximity accommodation and caregiver logistics for the four-week REMS-restricted period, and stay with the case through 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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