

## Abecma

Jordan · access guide

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

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

## Quick orientation

Abecma (idecabtagene vicleucel) is an autologous BCMA-directed chimeric antigen receptor T-cell therapy approved by the US Food and Drug Administration in March 2021 for adults with relapsed or refractory multiple myeloma. The April 2024 label update moved the indication to the third-line setting in patients who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and are refractory to lenalidomide. The product is manufactured by Bristol-Myers Squibb in collaboration with 2seventy bio. Abecma is not registered with the Jordan Food and Drug Administration (JFDA), and access for a Jordanian patient runs through the named-patient pathway combined with an autologous cell collection arranged at a CAR-T-authorized US center. This is an exceptionally complex case profile, and Reserve Meds is candid with families about both the logistical envelope and the cost envelope before any commitment is made.

## Why Jordanian patients ask about Abecma

Jordan has a strong tertiary oncology infrastructure for the region. The King Hussein Cancer Center (KHCC) in Amman is the principal national reference, a JCI-accredited facility with deep hematology-oncology expertise, an active bone marrow transplant program, and a clinical research footprint that runs Phase 2 and 3 myeloma protocols. The Royal Medical Services hospitals, Jordan University Hospital, King Abdullah University Hospital in Irbid, and the major private hospitals in Amman (Istishari Hospital, Specialty Hospital, Arab Medical Center) carry the broader oncology load. Even in this environment, families arrive at the Abecma question because triple-class-refractory myeloma exhausts the conventional armamentarium. By the time the hematologist is considering BCMA-directed CAR-T, the patient has typically cycled through lenalidomide-based induction, autologous stem cell transplant, proteasome inhibitor combinations, daratumumab-anchored salvage, and possibly elotuzumab, isatuximab, selinexor, or belantamab mafodotin. The conventional next step would be a clinical trial, a bispecific antibody such as teclistamab if available locally, or a second autologous transplant in a younger patient. For a subset of families, the conversation turns to BCMA CAR-T because the published response rates in heavily pretreated populations (overall response rate around 73 percent and complete response rate around 33 percent in the KarMMa pivotal trial) represent a step-change that no other available option matches.

The honest framing for a Jordanian family is that BCMA CAR-T is theoretically accessible through cross-border channels but is operationally one of the most demanding patient journeys in oncology. Unlike a small molecule or an antibody, Abecma requires that the patient's own T-cells be collected by leukapheresis, shipped under qualified conditions to the US manufacturing facility, manufactured into the CAR-T product over approximately three to five weeks, and shipped back to a CAR-T-authorized infusion center where lymphodepleting chemotherapy and infusion occur. The infusion itself is followed by a minimum two-week monitored stay for cytokine release syndrome and neurotoxicity surveillance under the REMS program.

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

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Jordan's regulatory framework for unregistered-medicine import runs through the Jordan Food and Drug Administration (JFDA) under the Drug and Pharmacy Law No. 12 of 2013 and its implementing regulations. The personal-use import permit is available where a JFDA-licensed physician documents the clinical necessity of a medicine that is not registered or not available in Jordan and for which no clinically equivalent locally registered alternative is suitable. For a BCMA-directed CAR-T therapy, the practical limitation is not the JFDA permit, which can issue for autologous cell therapy in principle, but the operational requirement that infusion occur at a CAR-T-authorized center with the appropriate REMS infrastructure. For Jordanian patients, this typically means either travelling to a designated CAR-T center in the United States, Europe, or one of the regional Gulf hubs that has stood up CAR-T capability, or arranging the autologous collection in Jordan with onward shipment to a US center for manufacturing and infusion.

A complete JFDA application for an autologous cell therapy includes the clinical justification letter from the treating hematologist documenting the prior treatment course, the refractory status, and the rationale for BCMA CAR-T as the appropriate next step; the treating physician's JFDA-recognized medical license verification (Jordan Medical Council and Ministry of Health registration); the destination infusion center identification and CAR-T accreditation (FACT certification or equivalent); the leukapheresis collection plan including the collecting center and the chain-of-custody arrangement; the BMS manufacturing slot reservation; and the post-infusion monitoring plan including the local Jordanian hematologist who will assume long-term follow-up.

JFDA processing for routine personal-use cases is typically 5 to 15 business days. For a CAR-T case, the application sits within a broader operational planning envelope that runs 8 to 16 weeks from first contact to infusion, with the JFDA component being only one of several gating elements.

## **Where Abecma cases are infused for Jordanian patients**

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Jordan does not currently operate a CAR-T-authorized infusion center for autologous BCMA cell therapy. The King Hussein Cancer Center has discussed CAR-T capability publicly and runs the autologous stem cell transplant program that is operationally closest to CAR-T, but the BCMA CAR-T REMS infrastructure is not in place for in-country infusion at the time of writing. Jordanian families who pursue Abecma therefore typically infuse at one of three categories of center: a US academic medical center with established CAR-T programs (MD Anderson Cancer Center in Houston, Memorial Sloan Kettering in New York, Dana-Farber Canc

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

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