Carvykti access in India: travel-for-treatment under the CDSCO framework

How Indian families with relapsed or refractory multiple myeloma orient to Carvykti (ciltacabtagene autoleucel) BCMA CAR-T therapy when they have specifically chosen the US-sourced product over the indigenous Indian CAR-T options, with apheresis-manufacture-return logistics and REMS-equivalent certified-centre handling built into the case plan.

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Quick orientation

Carvykti (ciltacabtagene autoleucel, often shortened to cilta-cel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell therapy from Janssen and Legend Biotech. Each dose is manufactured from the individual patient's own T-cells, collected via leukapheresis, engineered ex vivo to express a CAR construct targeting BCMA on myeloma plasma cells, expanded, and reinfused as a single intravenous infusion. The US Food and Drug Administration first approved Carvykti on 28 February 2022 for relapsed or refractory multiple myeloma after four or more prior lines of therapy, and on 5 April 2024 expanded the label to include patients who have received at least one prior line and are refractory to lenalidomide. India has its own indigenous CAR-T platforms (Immuneel Therapeutics' NexCAR19 for B-cell ALL and lymphoma, ImmunoACT/IIT-Bombay's HCAR-19 for B-cell ALL and lymphoma) approved by CDSCO and growing in clinical use, but those products are CD19-directed and indicated for distinct hematologic malignancies. For a multiple myeloma patient and family who have specifically chosen the BCMA-directed US-sourced Carvykti, the practical access route is cross-border travel-for-treatment to a Carvykti-qualified centre in the US, EU, UK, or Japan. The CDSCO Rule 36 framework supports the upstream documentation and any ancillary medicine flow, but the therapy itself is not administered in India and Reserve Meds frames Carvykti coordination as travel logistics rather than a typical NPP shipment.

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Why patients in India need Carvykti via cross-border coordination

India has a meaningful multiple myeloma caseload and a growing transplantation and BMT capacity at AIIMS New Delhi, Tata Memorial Centre Mumbai, Christian Medical College Vellore, Apollo Hospitals, Kokilaben, MGM Healthcare, Manipal, and Medanta. The country has also leaned into indigenous CAR-T capability. Immuneel Therapeutics' NexCAR19 and ImmunoACT's HCAR-19 (developed with IIT-Bombay and Tata Memorial) have established CDSCO-approved CD19-directed CAR-T programmes for B-cell acute lymphoblastic leukemia and B-cell lymphomas at clinical cost points materially below US BCMA CAR-T pricing. For some Indian families, the indigenous CD19 platforms are the right clinical answer when the indication aligns.

For myeloma specifically, the indication does not align with the Indian indigenous CD19 platforms. Multiple myeloma is a plasma cell malignancy expressing BCMA, not CD19. The Indian indigenous BCMA CAR-T pipeline is in clinical-trial stages rather than approved-for-

routine-use stages at the time of this review, and a myeloma patient with relapsed or refractory disease who has chosen BCMA CAR-T as the treatment plan is, in practice, choosing between Carvykti (Janssen/Legend) and Abecma (Bristol Myers Squibb / 2seventy bio) as the two FDA-approved BCMA CAR-T options. Carvykti is not registered with the CDSCO. Even where the molecule is registered in another jurisdiction, the operational chain required to deliver an autologous CAR-T (apheresis collection, manufacturing at a Janssen-Legend facility in Raritan, New Jersey or Ghent, Belgium, return shipment under continuous liquid-nitrogen vapor-phase cryogenic transport, lymphodepleting chemotherapy at the receiving infusion centre, infusion, and a structured monitoring window) is not available routinely in India for the Carvykti product specifically.

The realistic access route is travel to a Carvykti-qualified centre in the US, EU, UK, or Japan, where apheresis and infusion are performed in the destination country under the manufacturer's REMS-certified treatment-centre network. The patient and family stay in the destination country for the manufacturing cycle (approximately 30 to 45 days) and the post-infusion monitoring window (at least 4 weeks within proximity of the treatment centre, with driving restrictions extending to 8 weeks). The CDSCO Rule 36 framework supports any ancillary medicine flow back to India after the patient returns home, but the cell therapy itself is administered abroad.

The CDSCO Rule 36 framework for ancillary medicine in Carvykti cases

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment.

For Carvykti specifically, Rule 36 is not the primary access mechanism because the cell therapy is not shipped to India. The framework matters at the margins: any ancillary medicines that the patient brings home from the destination centre for ongoing care (such as prophylactic antimicrobials, immunoglobulin replacement for hypogammaglobulinemia management, or other supportive care medicines) may be subject to import documentation if they are unregistered locally. For institutional Compassionate Use of drugs not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. Both routes apply where the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for an unmet medical need. Government institutions including AIIMS New Delhi and Tata Memorial Centre Mumbai have established workflow for oncology compassionate use.

The Reserve Meds operational focus in a Carvykti case is upstream patient and family orientation rather than CDSCO filings: the apheresis-to-infusion cycle, the manufacturing window, the cost envelope including hospitalisation, the cold-chain reality at the destination centre, and the travel and stay logistics. The treating Indian hematologist remains in the decision loop and continues post-infusion follow-up after the family returns home, with coordination back to the destination centre for long-term durability monitoring (15 years per FDA guidance for CAR-T cell therapies).

Where Carvykti gets administered for Indian patients

Carvykti is shipped only to REMS-certified treatment centres that have completed Carvykti REMS Program training in cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome (ICANS) management. The product travels in the vapor phase of liquid nitrogen at temperatures at or below minus 150 degrees Celsius, in a liquid-nitrogen dry shipper with continuous temperature logging. There is no off-the-shelf inventory; each dose is patient-specific and tied to that patient's apheresis collection. Each dose is also linked to a specific manufacturing slot at Janssen-Legend's Raritan, New Jersey facility or the Ghent, Belgium site.

For Indian patients, this means selecting a destination treatment centre in a jurisdiction where Carvykti is registered and a qualified infusion network exists. In the US, NCI-designated cancer centres and qualifying academic medical centres make up the certified-centre network. In the EU and UK, EMA and MHRA equivalent risk-management frameworks govern the comparable certified-centre lists. PMDA Japan approved Carvykti in 2022 and operates its own certified-centre network. India does not have a Carvykti-qualified infusion centre at the time of this review, and BCMA-directed CAR-T access in the region runs primarily through King Faisal Specialist Hospital and Research Centre in Saudi Arabia where cell-therapy infrastructure has grown under named-patient and compassionate-use frameworks, though Carvykti specifically would still require sourcing through Janssen-Legend's manufacturing network.

The treating Indian hematologist (often at AIIMS New Delhi, Tata Memorial Centre Mumbai, Christian Medical College Vellore, Kokilaben, Apollo, MGM, or Manipal) typically coordinates the referral, the clinical workup, and the post-infusion follow-up after the family returns home. The destination centre carries the apheresis, the lymphodepleting chemotherapy (cyclophosphamide 300 mg/m2 IV and fludarabine 30 mg/m2 IV daily for 3 days starting 5 to 7 days before infusion), the infusion itself, and the structured at-least-daily monitoring for 10 days following infusion. Patients remain within proximity of the treatment centre for at least 4 weeks. Driving and operating heavy machinery are restricted for at least 8 weeks given the risk of delayed neurotoxicity.

Real cost picture for Carvykti for Indian patients

Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. Pricing in this section is expressed in USD for portability; the actual invoice converts at the prevailing rate on the day of the transaction.

Per Janssen launch pricing reported by Fierce Pharma, the US wholesale acquisition cost for Carvykti is approximately USD 465,000 per single-infusion dose. This figure covers the manufactured CAR-T product only. The total per-patient cost of care is materially higher: real-world all-in costs reported in US commercial and Medicare settings range from approximately USD 600,000 to over USD 1,000,000 per patient when leukapheresis, bridging therapy, lymphodepleting chemotherapy, the infusion, an inpatient or close-observation hospitalisation window of 1 to 2 weeks, outpatient monitoring through week 4, and management of any cytokine release syndrome, ICANS, or other adverse events are included. EU and UK pricing is generally negotiated at the national-health-system level and is not publicly disclosed in a standardised way.

For Indian families, the cost envelope must also include travel, accommodation for the patient and at least one caregiver across the 30-to-45-day manufacturing cycle plus the 4-week monitoring window plus the staged return-travel cycle, visa and immigration processing, and any pre-departure clinical workup costs. The Reserve Meds quote itemises the patient-side coordination charges separately from the destination centre's medical charges, which are billed

directly by the centre and which Reserve Meds does not mark up. The drug itself, the apheresis and infusion procedures, and the hospitalisation costs all sit on the destination centre's ledger.

None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Niva Bupa) reimburse a cross-border BCMA CAR-T treatment as a standard line item. CGHS and ESIC are not structured for cross-border CAR-T reimbursement. The NPRD 2021 INR 50 lakh ceiling is not aligned with the cost of US-sourced BCMA CAR-T even setting aside the cross-border travel-for-treatment structure. Cash-pay, frequently through diaspora-funded or family-pooled financial structures, is the operating posture.

Typical timeline for Carvykti for Indian patients

The Carvykti operational arc is the dominant timeline variable, not the CDSCO Rule 36 permit. From the patient's perspective, the cycle runs: clinical workup and destination-centre referral (commonly 4 to 8 weeks); travel and visa preparation (commonly 2 to 8 weeks depending on destination jurisdiction); apheresis collection at the destination centre (typically 1 day); manufacturing at a Janssen-Legend facility (approximately 30 to 45 days from apheresis to product release, depending on manufacturing slot availability and batch release testing); bridging therapy at the discretion of the treating hematologist during the manufacturing wait; lymphodepleting chemotherapy with cyclophosphamide and fludarabine over 3 days starting 5 to 7 days before infusion; the single Carvykti IV infusion; at-least-daily monitoring for 10 days post-infusion at the REMS-certified facility; and a continued monitoring window of at least 4 weeks within proximity of the centre for cytokine release syndrome, ICANS, and other immune-effector cell toxicities. Total time abroad commonly runs three to four months from arrival to return. Manufacturing slot availability has historically been the binding constraint on patient sequencing, though Janssen and Legend have publicly committed to capacity expansion and Q4 2025 sales of approximately USD 555 million per Legend's preliminary release reflect expanded throughput.

What your physician needs to provide

The clinical justification framework for Carvykti differs from a typical NPP filing because Rule 36 does not gate the cell therapy itself. The treating Indian hematologist's responsibility runs to documentation that supports the destination-centre referral: a confirmed diagnosis of relapsed or refractory multiple myeloma with the prior-lines-of-therapy documentation that aligns with the chosen indication (the 2022 approval requires at least four prior lines including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; the 2024 expansion permits use after at least one prior line if the patient is refractory to lenalidomide); current disease status with imaging and laboratory results; performance-status assessment; and a written referral to the destination centre's hematology team. The destination centre then runs its own intake assessment, including REMS-certified-facility readiness, vein access for apheresis, and the suitability of bridging therapy during the manufacturing wait.

Any ancillary medicines that the patient brings home from the destination centre for ongoing care, where those medicines are unregistered in India, route through standard Rule 36 with the treating Indian hematologist's prescription showing the NMC registration number and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation continuing for any imported product. Reserve Meds includes the PvPI reference in the relevant documentation kit; the reporting obligation itself stays with the prescribing physician.

Common questions about Carvykti in India

What about India's indigenous CAR-T options?

Immuneel Therapeutics' NexCAR19 and ImmunoACT/IIT-Bombay's HCAR-19 are CD19-directed CAR-T therapies approved by CDSCO for B-cell acute lymphoblastic leukemia and B-cell lymphomas. They are not BCMA-directed and are not indicated for multiple myeloma. For a myeloma patient considering BCMA CAR-T specifically, the indigenous Indian CD19 platforms are not the comparator. The two FDA-approved BCMA CAR-T options are Carvykti and Abecma; the treating hematologist makes the comparator decision. Reserve Meds does not advise on the BCMA CAR-T product choice and frames Carvykti coordination only where the patient and treating team have specifically chosen the US-sourced Carvykti.

What is the safety profile we should be aware of?

Carvykti carries an FDA boxed warning for cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome (ICANS), parkinsonism and Guillain-Barre syndrome, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, and prolonged or recurrent cytopenia. Each of these can be fatal or life-threatening. Hypogammaglobulinemia and serious infections are also common. Second primary malignancies, including T-cell malignancies, have been reported in the BCMA CAR-T class and are part of post-marketing surveillance. The destination treatment centre's REMS-certified team handles acute toxicity management; the treating Indian hematologist continues long-term follow-up after the family returns home.

Why Carvykti versus Abecma?

Both are FDA-approved BCMA-directed CAR-T therapies for multiple myeloma. The CARTITUDE trials (Carvykti) and KarMMa trials (Abecma) are separate programmes with different patient populations and follow-up durations. Selection turns on prior lines of therapy, manufacturing slot availability, treatment centre experience, and the treating hematologist's clinical judgment. Reserve Meds does not weigh in on this decision.

What is the typical course duration?

A single one-time IV infusion. The full operational arc from leukapheresis through the 4-week monitoring window at the destination centre is approximately 6 to 10 weeks. Total time abroad including pre-departure preparation, manufacturing wait, post-infusion monitoring, and staged return commonly runs three to four months. Long-term follow-up extends for 15 years per FDA guidance for CAR-T cell therapies.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa reimburse a cross-border Carvykti case?

None of the major Indian private insurers reimburse a cross-border BCMA CAR-T treatment as a standard line item. Some private insurers have reimbursed portions of overseas cancer treatment where the underlying medicine is in the formulary and the cross-border route was framed as the necessary access route; the operating expectation for Carvykti is cash-pay through diaspora-funded or family-pooled structures. Reserve Meds itemises the patient-side coordination charges separately from destination-centre medical charges so the family can pursue any reimbursement attempt with clean documentation.

Does FCRA affect a diaspora-funded Carvykti case?

The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the treatment themselves, including an adult child overseas paying for a parent's care, FCRA is generally not engaged. Where a foreign foundation or myeloma-focused diaspora group is funding the treatment, FCRA registration of the recipient organisation and the donation route can become relevant. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

Where Reserve Meds fits in Carvykti cases

Reserve Meds is a US-based concierge coordinator. We do not administer Carvykti, do not perform apheresis, do not run the manufacturing slot, and do not act as a clinical decision-maker. The coordination value sits at the upstream and downstream edges of the operational arc: helping the patient and family understand the apheresis-manufacture-return cycle, the timing, the monitoring window, the cost envelope, the cold-chain reality at the destination, and the travel-and-stay logistics of accompanying a patient abroad for three to four months. Reserve Meds will not coordinate a Carvykti case without a confirmed destination-centre acceptance, a confirmed treating-hematologist plan in India for pre-departure clinical workup and post-return follow-up, and confirmed cash-pay capacity at the relevant cost tier. The Reserve Meds Concierge Patient Coordinator carries the case from intake through return-to-India and into the long-term follow-up window with the treating Indian hematologist. No prior Reserve Meds case experience exists for Carvykti as of this review.

Next step

If an Indian patient with relapsed or refractory multiple myeloma has a treating hematologist considering BCMA CAR-T and the family has specifically chosen US-sourced Carvykti over comparator options, add the case to the waitlist. We will respond within 24 to 48 hours with an orientation memo on the operational arc, an indicative cost envelope, and the next-step questions for the destination-centre referral.

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