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Imdelltra access in India: the CDSCO Rule 36 named-patient pathway

How Indian patients with previously treated extensive-stage small cell lung cancer legally obtain Imdelltra (tarlatamab-dlle) from US-source supply when the medicine is not yet registered locally, with 22 to 24 hour inpatient monitoring readiness built into the case plan.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Imdelltra (tarlatamab-dlle) is the first DLL3-targeted bispecific T-cell engager approved by the US FDA. Accelerated approval was granted on 16 May 2024 and converted to traditional (full) approval on 19 November 2025 for adults with extensive-stage small cell lung cancer (ES-SCLC) whose disease has progressed on or after platinum-based chemotherapy. It is administered as an intravenous infusion only. There is no public record of Imdelltra registration in India (CDSCO) as of this review. Indian ES-SCLC patients reach the medicine through the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI), or through the institutional Compassionate Use route for hospitals like AIIMS New Delhi and Tata Memorial Centre Mumbai. Reserve Meds coordinates the US-side specialty wholesaler sourcing through Amgen's authorized channels under DSCSA serialization, validated 2 to 8 degree Celsius cold-chain logistics, and the documentation kit your medical oncologist needs to file.

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Why patients in India need Imdelltra via the named-patient pathway

India's oncology capability is deep. The National Cancer Grid anchored by Tata Memorial Centre Mumbai coordinates standard-of-care across more than 250 institutions. AIIMS New Delhi handles compassionate and named-patient imports as established workflow, including in thoracic oncology. Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis Healthcare, Medanta The Medicity, Kokilaben Mumbai, MGM Chennai, CMC Vellore, and Manipal Bangalore run JCI or NABH-accredited oncology programmes with chemotherapy day-care suites and inpatient capacity. What is missing for ES-SCLC patients post-platinum is a routinely stocked DLL3-targeted bispecific antibody on hospital formularies. Imdelltra is not registered with CDSCO as of this review; personal importation under Rule 36 is the legal route.

The clinical urgency is acute. ES-SCLC carries a poor prognosis, and the post-platinum setting historically had very few effective options. Before Imdelltra's 2024 approval, second-line ES-SCLC in most jurisdictions defaulted to topotecan, lurbinectedin where approved, or re-challenge with platinum-based chemotherapy. None of these match the response rate or response duration seen in the Imdelltra DeLLphi-301 trial in the platinum-pretreated population. SCLC progresses rapidly after platinum failure, and treatment delays cost meaningful time. Indian oncologists at expert thoracic-oncology centres routinely require US lot-level DSCSA traceability for a launch-phase biologic, which is the operating standard Reserve Meds maintains.

The CDSCO Rule 36 named-patient pathway for Imdelltra

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. The quantity of any single drug imported is capped at one hundred average doses per application.

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. This route applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for a life-threatening condition. ES-SCLC after platinum failure fits the life-threatening condition framing precisely. AIIMS New Delhi and Tata Memorial Centre Mumbai have established workflow for this pathway.

For Imdelltra specifically, the clinical-justification angle is precise. The strongest Form 12A applications consistently document: pathology-confirmed small cell lung cancer with extensive-stage disease; documentation of prior platinum-based chemotherapy with dates and the documented progression on or after that line; current performance status and relevant comorbidities; the rationale for Imdelltra over the available alternatives (topotecan, lurbinectedin where approved, platinum re-challenge); the proposed dosing plan following the FDA-labeled step-up schedule (Cycle 1 Day 1 at 1 mg, Cycle 1 Day 8 and Day 15 at 10 mg, then 10 mg every two weeks in maintenance until progression or unacceptable toxicity); and most critically the planned 22 to 24 hour inpatient monitoring readiness after the Cycle 1 Day 1 dose and the Cycle 1 Day 8 dose, with documentation that the dispensing institution can deliver inpatient observation, CRS readiness, and an ICANS-response plan. The kit composition (1 mg vial, 10 mg vial, and the IV Solution Stabilizer vial) ships together as a single unit; partial-kit sourcing is not viable. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where documentation is complete; first-time imports of a novel-mechanism BiTE biologic at an institution that has not previously stocked a DLL3-targeted product may run longer for institutional pharmacy review.

Where Imdelltra gets dispensed in India

Imdelltra requires a hospital with adult medical-oncology capacity, an infusion suite for the approximately one-hour IV administration, and inpatient or extended-monitoring capability for the 22 to 24 hour observation after the Cycle 1 Day 1 (1 mg) dose and the Cycle 1 Day 8 (10 mg) dose. Subsequent infusions require at least six to eight hours of post-infusion monitoring if prior infusions were tolerated. The Indian institutions that fit this profile and routinely handle named-patient oncology imports include AIIMS New Delhi (apex public-sector institution, oncology workflow for Compassionate Use), Tata Memorial Centre Mumbai (autonomous institution under the Department of Atomic Energy, India's oldest and largest cancer institute, anchor of the National Cancer Grid), Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata, with dedicated international patient services and JCI plus NABH accreditation), Fortis Healthcare (Fortis Memorial Research Institute Gurgaon, Mulund Mumbai, Bangalore, Kolkata), Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, Christian Medical College (CMC) Vellore, and Manipal Hospitals Bangalore.

For Imdelltra, the 22 to 24 hour inpatient monitoring requirement is the gating institutional capability. We will not coordinate Imdelltra delivery to a patient who is not under the care of a medical oncologist with admitting privileges at a facility capable of inpatient extended monitoring with CRS and ICANS readiness. For patients in smaller cities, the practical pattern is to route to AIIMS, Tata Memorial, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, or Manipal for at least the Cycle 1 step-up doses, with consideration of local maintenance dosing only after the first three doses have been completed without significant CRS.

Real cost picture for Imdelltra in India

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. US wholesale acquisition cost at the time of launch was approximately USD 31,500 for the first 28-day cycle (the 1 mg step-up dose, two 10 mg doses, and the IVSS components) and approximately USD 30,000 per subsequent 10 mg

infusion. Amgen-published estimated annualised cost is approximately USD 781,500 per year for a patient remaining on therapy continuously, before any rebates, US specialty-channel adjustments, or US-only Amgen patient assistance. At the prevailing USD/INR rate, the annualised US drug cost converts to approximately INR 7.34 crore per year.

International validated 2 to 8 degree Celsius cold-chain shipping for the every-two-week maintenance cadence typically runs USD 800 to 1,500 (approximately INR 75,000 to 1.4 lakh) per shipment depending on city of destination, urgency window, and whether multiple cycles are consolidated. CDSCO permit fees are nominal. India's Union Budget 2026-27 expanded customs-duty exemption on a set of named cancer medicines; the specific HSN code and exemption status of each Imdelltra shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5 percent. The dispensing hospital's infusion fees, the inpatient monitoring stay for the first two doses, premedication (dexamethasone, IV hydration of at least 1 litre of normal saline before and after), and supportive care for any CRS or neurologic events sit on the hospital's side of the ledger. Reserve Meds itemises the US-side procurement, the international cold-chain logistics, and the concierge coordination fee separately on every firm quote.

None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Apollo Munich, Niva Bupa) reimburse a Rule 36 personal import of an unregistered oncology biologic as a standard line item. CGHS provides for life-saving and anti-cancer medicines that are not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case, with stricter constraints on drugs not approved by DCGI. Cash-pay is the operating default. Ayushman Bharat PMJAY does not, in practice, cover most expensive originator specialty drugs for advanced oncology.

Typical timeline for Imdelltra in India

For a routine Indian Imdelltra case at an established oncology institution, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing, per the regulator's published guidance. The cold-chain biologic class adds two to three days to international transit windows compared with ambient products. Validated 2 to 8 degree Celsius shipping is rated for 72 to 120 hours, which dictates route selection and customs-clearance timing at Delhi, Mumbai, Bengaluru, Chennai, or Hyderabad airports. A first-time Imdelltra import at an institution that has not previously stocked a DLL3-targeted BiTE may add two to four weeks for institutional pharmacy onboarding, confirmation of inpatient monitoring capacity, and CRS and ICANS readiness review. End-to-end, families typically plan for three to six weeks from oncologist decision to Cycle 1 Day 1 dose. Because Imdelltra is dosed every two weeks in maintenance after the Cycle 1 step-up schedule, Reserve Meds quotes patients for an initial sourcing window (typically the first two to three cycles) and re-quotes ongoing access as treatment continues.

What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Imdelltra, the strongest letters consistently include: pathology-confirmed small cell lung cancer with extensive-stage disease, with the staging documentation and any relevant imaging; documentation of prior platinum-based chemotherapy regimens with dates and the documented progression on or after that line; current performance status (ECOG) and relevant comorbidities including any prior CNS involvement; the rationale for Imdelltra over topotecan, lurbinectedin where approved, or platinum re-challenge; the proposed dosing plan following the FDA-labeled step-up schedule (Cycle 1 Day 1 at 1 mg, Cycle 1 Day 8 and Day 15 at 10 mg, then 10 mg every two weeks); the planned monitoring plan including 22 to 24 hours of post-infusion monitoring after the first two doses with explicit CRS and ICANS readiness language; the premedication plan (intravenous dexamethasone or equivalent before the first two doses, plus IV hydration of at least one litre of normal saline before and after these infusions); and the prescribing oncologist's NMC registration number. The dispensing institution's drug licence, the chain-of-custody plan from the US specialty wholesaler to the Indian hospital pharmacy, and the patient identifier complete the file.

The treating oncologist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation. Reserve Meds includes the PvPI reference in the physician documentation kit; the reporting obligation itself sits with the prescribing physician.

Common questions about Imdelltra in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Imdelltra?

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered oncology biologic as a standard line item. Some plans have considered case-by-case reimbursement for oncology indications with documented prior-line failure. Reserve Meds provides the itemised documentation that lets the insurer evaluate. Cash-pay is the operating default.

What is the safety profile we should be aware of?

The Imdelltra FDA label carries a boxed warning for cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). In the DeLLphi-301 trial, CRS occurred in approximately 51 percent of patients on the 10 mg dose, with most events being grade 1 or 2 and occurring during Cycle 1. Other common adverse reactions in over 20 percent of patients included fatigue, pyrexia, dysgeusia (taste alteration), decreased appetite, musculoskeletal pain, constipation, anemia, and nausea. Patients should be advised not to drive or operate heavy machinery for 48 hours after each infusion because of the risk of neurologic events.

What is the inpatient monitoring requirement?

Patients must be monitored in an appropriate healthcare setting for 22 to 24 hours after the Cycle 1 Day 1 (1 mg) dose and after the Cycle 1 Day 8 (10 mg) dose. Subsequent infusions require at least six to eight hours of post-infusion monitoring if prior infusions were tolerated. Reserve Meds confirms the receiving facility's capacity to meet this requirement as part of intake clinical review; an oncology centre without inpatient extended-monitoring capability is not an acceptable destination for the first two Imdelltra doses.

Will my MoH-affiliated or government-medical-college oncologist's letter be sufficient?

Yes. Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. Oncologists at AIIMS, Tata Memorial, government medical colleges, and state-run tertiary hospitals routinely sign these letters. Private-sector oncologists at Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal also have signing authority subject to their institutional drug licence and the dispensing hospital's inpatient monitoring capacity.

Is there a competitor or alternative?

In the post-platinum ES-SCLC setting, alternatives include topotecan (intravenous or oral), lurbinectedin where approved, and platinum re-challenge for selected patients. None of these are DLL3-targeted; Imdelltra is the only approved DLL3 BiTE. The choice between options is the treating oncologist's clinical decision based on patient-specific factors including prior therapy, performance status, comorbidities, prior CNS involvement, and access. Reserve Meds does not select therapy.

What is the typical course duration?

Treatment continues until disease progression or unacceptable toxicity; there is no fixed-cycle endpoint. Median duration of treatment in the pivotal trial at data cutoff was several months, but responders can remain on therapy substantially longer.

Where Reserve Meds fits in Imdelltra cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, do not replace CDSCO or the DCGI, and do not replace the dispensing hospital pharmacy or the licensed specialty importer. What we do is orchestrate the US-side specialty wholesaler sourcing through Amgen's authorized network under DSCSA serialization with full pedigree, validated 2 to 8 degree Celsius cold-chain logistics with IATA-compliant validated shippers and continuous temperature monitoring through to handoff, and the documentation kit your oncologist needs for the Form 12A filing. The kit

composition (1 mg vial, 10 mg vial, and the IVSS vial) ships together as a single unit; partial-kit sourcing is not viable. No prior Reserve Meds case experience exists for Imdelltra in India as of this review, so standard NPP coordination applies with particular attention to the dispensing institution's 22 to 24 hour inpatient monitoring capacity and CRS plus ICANS readiness. A single named coordinator carries the case from intake through Cycle 1 step-up and into the every-two-week maintenance cadence.

Next step

If an Indian patient with extensive-stage small cell lung cancer has progressed on or after platinum-based chemotherapy and the treating oncologist is considering Imdelltra, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your oncologist and an indicative cost range.

Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a licensed Indian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.