Imdelltra access in Pakistan via the DRAP named-patient pathway

How patients in Pakistan obtain Imdelltra (tarlatamab-dlle) for extensive-stage small cell lung cancer after platinum-based chemotherapy, through the Drug Regulatory Authority of Pakistan Special Permission / Personal Use Import pathway.

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

1. Quick orientation

Imdelltra is the brand name for tarlatamab-dlle, a bispecific T-cell engager (BiTE) that binds DLL3 on small cell lung cancer (SCLC) tumor cells with one arm and CD3 on cytotoxic T cells with the other. The US Food and Drug Administration granted accelerated approval on May 16, 2024 for adults with extensive-stage SCLC (ES-SCLC) whose disease has progressed on or after platinum-based chemotherapy, and converted the approval to traditional full approval on November 19, 2025. In Pakistan, families with a relapsed or refractory ES-SCLC diagnosis at one of the tertiary oncology centers in Karachi, Lahore, or Islamabad face a setting with very few effective second-line options. The Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import pathway, filed through the Online Import and Export System (OIES) portal, is the lawful route once a Pakistan Medical and Dental Council (PMDC) licensed medical oncologist has decided this is the right next step. Reserve Meds is the US-side coordinator that aligns the sourcing, the cold-chain logistics, and the regulatory documentation kit your treating physician and hospital pharmacy need. Reserved for you.

2. Why patients in Pakistan need Imdelltra via NPP

ES-SCLC carries a poor prognosis, and the post-platinum setting historically 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 phase 2 trial in the platinum-pretreated population, and Imdelltra is the only approved DLL3-targeted bispecific. There is no public record of DRAP registration of Imdelltra at the time of this review. Pakistan's specialty drug market has matured around a small number of large private-sector tertiary hospitals, but the gap between FDA availability and on-shelf availability in Pakistan remains real for launch-phase oncology biologics.

Clinical urgency in this setting is high. SCLC progresses rapidly after platinum failure and treatment delays cost patients meaningful survival time. Pakistani families with an oncology patient at Aga Khan University Hospital (AKUH) in Karachi or Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore frequently look across borders because the alternative is no DLL3-targeted option at all. Families fund care through household pools that often draw on overseas remittances from relatives in Saudi Arabia, the UAE, the UK, the United States, and Canada. The named-patient pathway is the recognized regulatory route, and DSCSA-traceable US sourcing through a specialty wholesaler is the lot-level integrity standard that the receiving oncology team needs for a launch-phase biologic.

3. The DRAP Special Permission pathway for Imdelltra

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES). Institutional applications for oncology biologics are filed by the hospital pharmacy under its institutional license.

For Imdelltra specifically, the application package contains:

- **Clinical justification letter** from the treating medical oncologist, addressing histologically confirmed extensive-stage small cell lung cancer, prior-line platinum-based chemotherapy with documented outcome, progression on or after platinum, the rationale for a DLL3-directed bispecific T-cell engager, and the planned step-up dosing schedule.
- **PMDC licensure verification** for the treating medical oncologist.
- **Infusion-center capability attestation** from the hospital pharmacy and oncology service, confirming the facility can deliver the 22 to 24 hour post-infusion monitoring required after the Cycle 1 Day 1 (1 mg) and Cycle 1 Day 8 (10 mg) doses, has dexamethasone premedication and IV hydration protocols in place, and is equipped to manage cytokine release syndrome (CRS) and ICANS-type neurologic events.
- **Patient identifier:** CNIC for adult patients (Imdelltra is approved for adults; pediatric use is not labeled).
- **Product details** including brand name (Imdelltra), international nonproprietary name (tarlatamab-dlle), manufacturer (Amgen Inc., Thousand Oaks, California), country of origin (USA), kit composition (1 mg vial and 10 mg vial plus IV Solution Stabilizer (IVSS) vial in the same kit), pack size, requested quantity for the initial sourcing window, lot, and expiry. Partial-kit sourcing is not viable.
- **Destination dispensing facility license** showing the receiving infusion pharmacy is licensed to handle imported biologics with 2 to 8 degree Celsius cold-chain storage.
- **Manufacturer or authorized distributor letter** confirming the product is genuine and was sourced through Amgen's authorized US specialty channel under DSCSA serialization.
- **Chain-of-custody plan** from the US specialty wholesaler through international air freight (validated 2 to 8 degree Celsius packaging, continuous temperature monitoring, IATA-compliant cold-chain class C) to the receiving Pakistani facility, including the freight forwarder, customs broker for FBR clearance at the Karachi seaport or Lahore airport, and importer of record.

Routine personal-use cases typically clear in four to eight weeks from a complete submission. Cases involving novel-mechanism oncology biologics with CRS monitoring requirements can extend to ten to sixteen weeks. Reserve Meds plans on the longer end and treats any faster turnaround as upside.

4. Where Imdelltra gets dispensed in Pakistan

Imdelltra requires a 2 to 8 degree Celsius cold-chain handoff, an inpatient or extended-observation infusion suite capable of 22 to 24 hour post-infusion monitoring at Cycle 1 Day 1 and Cycle 1 Day 8, IV hydration and dexamethasone premedication protocols, and a medical oncology team trained to recognize and manage cytokine release syndrome and ICANS-type neurologic events. That capability set narrows the realistic dispensing footprint to flagship adult oncology centers. Aga Khan University Hospital (AKUH) Karachi operates the Department of Oncology with eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology, and pharmacy services with 24/7 temperature-controlled storage. Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore is Pakistan's flagship cancer hospital with the inpatient infusion and oncology pharmacy infrastructure to support a launch-phase BiTE. Indus Hospital and Health Network in Karachi has strong oncology and hematology capability. Liaquat National Hospital in Karachi and Shifa International Hospital in Islamabad handle named-patient oncology biologic imports as an established workflow.

Reserve Meds will not coordinate Imdelltra delivery to a patient who is not under the care of an oncologist with admitting privileges at a facility capable of the 22 to 24 hour post-infusion monitoring the FDA label requires.

5. Real cost picture for Imdelltra in Pakistan

Three line items make up the patient-facing cost of an Imdelltra case sourced from the United States into Pakistan.

Drug acquisition. Amgen-published US wholesale acquisition cost (WAC) at US launch was approximately USD 31,500 for the first 28-day cycle (which includes 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 estimated annualized cost is approximately USD 781,500 per year for a patient remaining on therapy continuously. Reserve Meds quotes in USD as the primary currency because the Pakistani Rupee has been volatile. At the current USD to PKR range of approximately 278 to 280 as of May 2026, the first-cycle drug-only cost lands around PKR 8.8 million at the WAC reference, with annualized PKR equivalents above PKR 217 million at continuous dosing.

International logistics surcharge. Validated 2 to 8 degree Celsius shipping with continuous temperature monitoring, IATA-compliant cold-chain class C packaging, customs documentation, and importer-of-record handling typically add USD 1,000 to USD 1,800 per shipment for Imdelltra. Because dosing is every two weeks after Cycle 1, shipment cadence and consolidation strategy meaningfully affect the annual logistics line. FBR customs clearance at the Karachi seaport or Lahore airport adds friction that experienced specialty importers manage routinely.

Coordination, documentation, and concierge fee. Reserve Meds quotes the concierge fee transparently on every case, with the rate disclosed on the firm quote rather than buried in a bundled total. The fee covers documentation kit preparation, US sourcing, cold-chain orchestration, customs paperwork, and a single named coordinator from intake through reorders.

Infusion administration, inpatient monitoring stays, CRS management consumables, and physician oversight are billed by the receiving Pakistani institution and are not part of the Reserve Meds quote. Local insurer behavior on named-patient imports is conservative: Adamjee, Jubilee, EFU, and State Life typically do not reimburse imported unregistered specialty drugs. Reserve Meds typically quotes patients for an initial sourcing window (often Cycle 1 plus the first 2 to 3 maintenance cycles) with the understanding that ongoing access is re-quoted as treatment continues.

6. Typical timeline for Imdelltra in Pakistan

From the date the clinical justification letter is signed and the OIES file is submitted, routine DRAP review for Imdelltra typically runs four to eight weeks. Cases involving launch-phase oncology biologics with CRS monitoring requirements can extend toward ten to sixteen weeks while institutional pharmacy committees and onboarding for the inpatient monitoring protocol are completed. Cold-chain transit adds approximately two to three days versus ambient air freight, so US-side procurement, validated packaging, and IATA-compliant freight booking tend to overlap with DRAP review rather than wait for it. Cycle 1 sets a specific operational rhythm: Day 1, Day 8, and Day 15 doses must land in a documented sequence with the 22 to 24 hour monitoring windows scheduled in advance. Reserve Meds plans the Cycle 1 logistics together with the receiving hospital pharmacy at case acceptance.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the DRAP submission. For an Imdelltra Personal Use Import application, the letter typically covers the following.

- **Diagnosis and disease history.** Histologically confirmed small cell lung cancer at extensive stage, with prior-line platinum-based chemotherapy documented (regimen, cycles delivered, best response, date of progression).
- **Disease status.** Imaging documentation of progression on or after platinum, performance status, prior CNS involvement, and key comorbidities relevant to CRS risk.
- **Mechanism rationale.** Why a DLL3-directed bispecific T-cell engager is appropriate at this point in the patient's course, in line with the FDA-labeled indication for adults with ES-SCLC whose disease has progressed on or after platinum-based chemotherapy.
- **Dosing plan.** Cycle 1 Day 1: 1 mg IV (step-up dose) over 1 hour. Cycle 1 Day 8: 10 mg IV over 1 hour. Cycle 1 Day 15: 10 mg IV over 1 hour. Cycle 2 and beyond: 10 mg IV every 2 weeks until disease progression or unacceptable toxicity.

- **Monitoring plan.** 22 to 24 hour post-infusion monitoring after Cycle 1 Day 1 and Cycle 1 Day 8; at least 6 to 8 hours of monitoring after subsequent doses if prior infusions were tolerated. Dexamethasone (or equivalent) premedication plus at least 1 liter of normal saline before and after the first two doses. Patient counseling not to drive or operate heavy machinery for 48 hours after each infusion.
- **Safety plan.** Institutional readiness for CRS and neurologic event management.
- **Adverse-event reporting commitment.** The treating physician's commitment to report adverse events through the DRAP Pharmacovigilance Centre, signed under the PMDC license.

8. Common questions about Imdelltra in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Imdelltra? Coverage for named-patient imports of unregistered drugs is uncommon across Pakistani health plans. Some plans pay a partial percentage on a case-by-case basis. Reserve Meds supplies the documentation an insurer would need to assess a claim; the claim itself is yours or your hospital's to file. The realistic default is cash-pay.

How does Sehat Sahulat interact with an Imdelltra case? The Sehat Sahulat Program's annual ceiling of Rs. 1,000,000 per family typically does not stretch to cover US-sourced specialty oncology biologics. Patients can still use Sehat Sahulat for hospitalization, supportive oncology care, and the inpatient monitoring stays while Imdelltra is procured separately on a cash-pay basis.

Can Imdelltra be administered at home? No. Imdelltra is an IV infusion that requires monitoring in an appropriate healthcare setting for 22 to 24 hours after Cycle 1 Day 1 and Cycle 1 Day 8, and at least 6 to 8 hours after subsequent infusions. Direct-to-home administration is not the model.

What is the safety profile? The 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% of patients on the 10 mg dose, with most events grade 1 or 2 and occurring during Cycle 1. Other common adverse reactions reported in over 20% of patients included fatigue, pyrexia, dysgeusia, decreased appetite, musculoskeletal pain, constipation, anemia, and nausea.

Is there an alternative? In the post-platinum ES-SCLC setting, alternatives include topotecan (IV or oral), lurbinectedin (where approved), and platinum re-challenge for selected patients. None are DLL3-targeted. The choice is a treating-physician decision based on patient-specific factors including prior therapy, performance status, comorbidities, prior CNS involvement, and access. Reserve Meds does not make this decision.

Our family pools funds across Pakistan and overseas. How does Reserve Meds handle that? Pakistan's diaspora pattern is well-established. Reserve Meds quotes in USD, accepts wire transfers from any USD-accessible source, and works with families coordinating funds across multiple countries before treatment can start.

9. Where Reserve Meds fits in Imdelltra cases

Reserve Meds has no prior Pakistan Imdelltra case experience as of the review date. Standard NPP coordination applies, with particular attention to four operational realities: treating-physician and infusion-center qualification (Reserve Meds will not coordinate delivery to a facility unable to deliver the 22 to 24 hour post-infusion monitoring); country authority pre-clearance as the default sequence; cold-chain integrity from US specialty wholesaler through FBR customs at 2 to 8 degrees Celsius with full kit (drug vials plus IVSS) shipping together; and Cycle 1 sequencing planned at case acceptance because Day 1, Day 8, and Day 15 must land in a documented sequence. The clinical decisions remain with the PMDC-licensed medical oncologist. The regulatory authority remains DRAP. The dispensing remains with the licensed Pakistani facility. Reserve Meds is the connective tissue between the US specialty wholesaler and those three Pakistani pillars, with a single named coordinator who stays with the case through reorders.

10. Next step

If you have a patient with relapsed or refractory extensive-stage small cell lung cancer in your family and a treating oncologist in Pakistan ready to write the clinical justification letter, the next step is to add your case to the waitlist so Reserve Meds can confirm eligibility within 24 to 48 hours and send the documentation kit to your physician and hospital pharmacy.

Reserved for you.

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