Imdelltra access in Saudi Arabia via the SFDA named-patient pathway

How patients in the Kingdom of Saudi Arabia obtain Imdelltra (tarlatamab-dlle) for previously treated extensive-stage small cell lung cancer, through the Saudi Food and Drug Authority Personal Importation Program.

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

1. Quick orientation

Imdelltra is the brand name for tarlatamab-dlle, the first DLL3-targeted bispecific T-cell engager (BiTE) biologic to receive FDA approval. The US Food and Drug Administration granted accelerated approval on May 16, 2024 and converted that to traditional (full) approval on November 19, 2025 for the treatment of adults with extensive-stage small cell lung cancer (ES-SCLC) whose disease has progressed on or after platinum-based chemotherapy. For patients in Saudi Arabia diagnosed with relapsed or refractory ES-SCLC, where local treatment options after platinum failure are limited and Imdelltra is not yet commercially available, the Saudi Food and Drug Authority (SFDA) Personal Importation Program (PIP) is the lawful, documented route. Reserve Meds is the US-side coordinator that aligns the sourcing, the cold-chain logistics, and the regulatory documentation kit your treating oncologist needs. Reserved for you.

2. Why patients in Saudi Arabia need Imdelltra via NPP

ES-SCLC carries a poor prognosis, and the post-platinum setting historically had very few effective options. Until Imdelltra's 2024 approval, second-line ES-SCLC treatment 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 phase 2 trial in the platinum-pretreated population. Imdelltra is the only approved DLL3-targeted BiTE, and it is not yet commercially available in Saudi Arabia. SFDA has no public registration record for Imdelltra as of the review date.

This is the cleanest named-patient profile in oncology: a recently approved, mechanistically novel biologic with no locally registered alternative in the same class, for a high-mortality indication where treatment delay measurably costs patients survival time. Saudi tertiary oncology centers in Riyadh, Jeddah, and the Eastern Province routinely identify ES-SCLC patients who have failed first-line platinum-based chemotherapy and are candidates for Imdelltra under the FDA-labeled indication.

Reserve Meds positions Imdelltra as a Tier-1 access case where the operational drivers are unbroken cold-chain handling, kit-level shipment integrity (drug vials plus IV Solution Stabilizer must travel together), DSCSA-traceable US sourcing through Amgen's authorized specialty channel, and destination-institution readiness for the 22 to 24 hour inpatient monitoring window required by the FDA label.

3. The SFDA Personal Importation Program for Imdelltra

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (US FDA for Imdelltra) and a clinically equivalent locally registered alternative is not suitable. The framework explicitly contemplates oncology therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, with named-patient activity increasingly routed through the agency's Ghad digital regulatory platform.

For Imdelltra specifically, the application package contains:

- **Clinical justification letter** from the treating oncologist, addressing diagnosis with ICD-10 coding (C34.x for malignant neoplasm of bronchus and lung, with small cell histology confirmation), staging documenting extensive-stage disease, prior platinum-based chemotherapy regimen with start and stop dates and the date and pattern of progression, and the rationale for a DLL3-targeted bispecific T-cell engager in this clinical setting.
- **SCFHS licensure verification** in medical oncology or hematology-oncology with admitting privileges at a facility capable of 22 to 24 hour post-infusion inpatient monitoring.
- **Inpatient infusion-monitoring capability documentation.** The FDA label requires monitoring in an appropriate healthcare setting for 22 to 24 hours after the Cycle 1 Day 1 (1 mg) dose and the Cycle 1 Day 8 (10 mg) dose because cytokine release syndrome (CRS) risk is highest at these step-up exposures. The PIP file should reflect that this monitoring capacity is in place.
- **Patient identifier** in the format SFDA requires, typically an anonymized internal reference linked to the national ID inside the hospital record.
- **Product details** including brand name (Imdelltra), international nonproprietary name (tarlatamab-dlle), manufacturer (Amgen Inc.), country of origin (USA), kit composition (1 mg vial or 10 mg vial plus IV Solution Stabilizer vial), J-code J9026, requested quantity for the initial sourcing window (typically the Cycle 1 induction kit plus initial maintenance doses), lot, and expiry.
- **Destination dispensing facility license** showing the receiving oncology pharmacy is SFDA-licensed to handle imported biologics with cold-chain storage and aseptic compounding capability.
- **Chain-of-custody plan** from the US specialty wholesaler through international transit with validated 2 to 8 degree Celsius packaging, continuous temperature monitoring, and kit-level integrity, to the receiving Saudi pharmacy, including freight forwarder, customs broker, and importer of record.

Approval timelines for routine cases typically run 10 to 21 business days. Complex cases, which can include first-time imports of a launch-phase oncology biologic such as Imdelltra at a given institution, can extend to 6 to 10 weeks. SFDA does not publish guaranteed turnaround times.

4. Where Imdelltra gets dispensed in Saudi Arabia

Imdelltra requires a 2 to 8 degree Celsius cold-chain handoff, an oncology infusion pharmacy capable of aseptic reconstitution and IV Solution Stabilizer compounding, and an inpatient bed for the 22 to 24 hour post-infusion monitoring window for the Cycle 1 Day 1 and Day 8 doses. That capability set narrows the realistic dispensing footprint to tertiary cancer centers. In Saudi Arabia, the institutions with the full stack in place include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network in Riyadh and Jeddah; King Saud University Medical City (KSUMC) and KSAU-HS affiliated centers; the Dr. Sulaiman Al Habib Medical Group (HMG) network across Riyadh, Jeddah, and the Eastern Province; Saudi German Health facilities; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh.

Smaller hospitals are not appropriate dispensing sites for Imdelltra. The 22 to 24 hour CRS observation requirement, the ICANS-aware nursing capacity, and the cold-chain and aseptic compounding infrastructure together make a tertiary cancer center the operating expectation. Reserve Meds will not coordinate Imdelltra delivery to a patient who is not under the care of an oncologist with admitting privileges at such a facility.

5. Real cost picture for Imdelltra in Saudi Arabia

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

Drug acquisition. US wholesale acquisition cost (WAC) at the time of 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 IV Solution Stabilizer components) and approximately USD 30,000 per subsequent 10 mg infusion. Amgen-published estimated annualized US cost is approximately USD 781,500 per year for a patient remaining on therapy continuously. At WAC reference, that translates to roughly SAR 2.93 million annualized for a patient on continuous therapy. Reserve Meds confirms current pricing at quote-build time because launch-phase biologics can see WAC adjustments year over year.

International logistics surcharge. Validated 2 to 8 degree Celsius shipping with continuous temperature monitoring, kit-level integrity, customs documentation, and importer-of-record handling typically adds SAR 3,500 to SAR 11,000 per shipment for Imdelltra, with the higher end reflecting the first kit (which carries the induction sequence) and consolidated cycles.

Coordination, documentation, and concierge fee. Reserve Meds quotes the concierge fee transparently on every case, with the rate disclosed on the firm quote. The fee covers documentation kit preparation, US sourcing through Amgen's authorized specialty channel, cold-chain orchestration, customs paperwork, and a single named coordinator from intake through reorders.

Local oncology infusion administration, premedication, 22 to 24 hour inpatient bed days for the Cycle 1 monitoring, CRS rescue capacity, and physician oversight are billed by the receiving Saudi institution and are not part of the Reserve Meds quote. Local insurer behavior on launch-phase oncology biologics varies. Bupa Arabia, Tawuniya, and MedGulf each handle named-patient imports case-by-case under the Council of Cooperative Health Insurance (CCHI) framework, with pre-authorization typically required.

6. Typical timeline for Imdelltra in Saudi Arabia

From the date the clinical justification letter is signed and the PIP file is submitted, routine SFDA review for Imdelltra typically runs 10 to 21 business days. First-time imports of a launch-phase oncology biologic at an institution can extend toward the 6 to 10 week range while internal pharmacy committees, the importer, and the inpatient oncology service onboard the protocol. Cold-chain transit adds approximately 2 to 3 days versus ambient air freight. Limited-distribution sourcing latency at the US specialty channel can add additional days. After the initial Cycle 1 induction kit is delivered and the Day 1 and Day 8 doses are administered with the required inpatient monitoring, the every-two-week maintenance cadence sets the rhythm: Reserve Meds plans the multi-cycle shipment cadence at case acceptance rather than treating each shipment as a one-off, because given the urgency of post-platinum ES-SCLC, dosing-interval discipline matters.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA submission. For an Imdelltra PIP application, the letter typically covers the following.

- **Diagnosis and staging.** Histologically confirmed small cell lung cancer, extensive-stage at the time of treatment decision, with the pathology report referenced.
- **Prior-line documentation.** The platinum-based first-line regimen, start and stop dates, response, and the date and pattern of progression on or after platinum-based chemotherapy. This is the FDA-labeled gating criterion.
- **Mechanism rationale.** Why a DLL3-targeted bispecific T-cell engager is appropriate at this disease state, in line with the FDA-labeled indication.
- **Dosing plan.** Cycle 1 Day 1 at 1 mg IV (step-up dose), Day 8 at 10 mg IV, Day 15 at 10 mg IV, then 10 mg IV every 2 weeks from Cycle 2 onward, until disease progression or unacceptable toxicity. Premedication with intravenous dexamethasone (or equivalent) before the first two doses and intravenous hydration with at least 1 liter of normal saline before and after these infusions.
- **Monitoring plan.** 22 to 24 hour inpatient observation after the Cycle 1 Day 1 (1 mg) dose and the Cycle 1 Day 8 (10 mg) dose. At least 6 to 8 hours of post-infusion monitoring for subsequent doses if prior infusions were

tolerated. Patient counseling not to drive or operate heavy machinery for 48 hours after each infusion. CRS and ICANS monitoring protocols in place.

- **Adverse-event reporting commitment.** The treating physician's commitment to report any adverse event through the SFDA National Pharmacovigilance Center, signed under the SCFHS license.

Reserve Meds supplies a documentation kit that maps each of these elements to the SFDA-required sections, so the physician is not building the file from scratch.

8. Common questions about Imdelltra in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Imdelltra? Each plan handles named-patient imports case-by-case under CCHI rules. Pre-authorization is typically required for a launch-phase oncology biologic at this price point, and reimbursement, where available, often comes after the fact through the patient's own claim. Cash-pay is the default operating posture.

Can a Ministry of Health oncologist sign the PIP letter? Yes. KSA-licensed oncologists at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license, as do private-sector oncologists at HMG, Saudi German, Fakeeh, Dallah, and similar tertiary facilities.

Does the patient really need to be admitted overnight for the first two doses? Yes. The FDA label requires 22 to 24 hour monitoring in an appropriate healthcare setting after Cycle 1 Day 1 and Cycle 1 Day 8 because the risk of cytokine release syndrome is highest at these step-up exposures. Reserve Meds confirms this monitoring capacity is in place as part of intake clinical review before procurement is initiated.

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 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 reported in over 20 percent of patients included fatigue, pyrexia, dysgeusia, decreased appetite, musculoskeletal pain, constipation, anemia, and nausea.

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. Reserve Meds typically quotes patients for an initial sourcing window (often the first two to three cycles) with the understanding that ongoing access is re-quoted as treatment continues.

Is there a comparator? In the post-platinum ES-SCLC setting, alternatives include topotecan, lurbinectedin where approved, and platinum re-challenge for selected patients. None of these are DLL3-targeted. The selection between Imdelltra and these alternatives is a treating-physician decision based on patient-specific factors.

9. Where Reserve Meds fits in Imdelltra cases

Reserve Meds has no prior Saudi Imdelltra case experience as of the review date. Standard NPP coordination applies, with three operating notes specific to this product: treating-physician and infusion-center qualification is mandatory (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 22 to 24 hour post-infusion monitoring); country authority pre-clearance is the default sequence (SFDA file evidence before US sourcing is initiated); and the product is a kit, so kit-level shipment integrity from US wholesaler through customs is part of the chain-of-custody plan. The clinical decisions remain with the SCFHS-licensed oncologist. The regulatory authority remains SFDA. The dispensing remains with the licensed Saudi hospital pharmacy. Reserve Meds is the connective tissue between the US specialty wholesaler and those three Saudi pillars.

10. Next step

If your treating oncologist in Saudi Arabia has identified Imdelltra as the appropriate next line of therapy after platinum-based chemotherapy and your treating institution can meet the 22 to 24 hour monitoring requirement, 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.

Reserved for you.

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