Imdelltra access in Egypt: the EDA Personal Importation pathway

How patients in Egypt 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.

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Quick orientation

Imdelltra (tarlatamab-dlle) is the first DLL3-targeted bispecific T-cell engager approved by the US Food and Drug Administration. The agency granted accelerated approval in May 2024 and converted to traditional approval in November 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. In Egypt, Imdelltra has no public record of registration, and Egyptian thoracic oncologists treating patients with relapsed ES-SCLC reach the medicine through the Egyptian Drug Authority (EDA) Personal Importation pathway under Law No. 151 of 2019. An Egyptian-licensed medical oncologist with admitting privileges at a facility capable of 22 to 24 hour post-infusion monitoring files the application through a licensed dispensing hospital. Reserve Meds handles the US-side sourcing, cold-chain logistics, and the documentation kit your physician needs.

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

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 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 duration seen in the Imdelltra DeLLphi-301 phase 2 trial in the platinum-pretreated population. In Egypt, the access gap is straightforward. There is no public record of Imdelltra registration with EDA at this review date, which means commercial stocking through any Egyptian hospital pharmacy or licensed importer is absent. The clinical urgency in this setting is high, because SCLC progresses rapidly after platinum failure and treatment delays cost patients meaningful survival time. The European Medicines Agency CHMP adopted a positive opinion for tarlatamab under the EU brand Imdylltra in March 2026, with European Commission marketing authorisation expected to follow, but EU registration does not translate into Egyptian availability through standard commercial channels.

The Egyptian patient population pursuing Imdelltra is concentrated at adult medical oncology services, not at the pediatric 57357 hospital. Adult ES-SCLC referrals route to Cairo University Hospitals, Ain Shams University Hospitals, the National Cancer Institute (Cairo University affiliate), and the major private oncology centres in Cairo. Cash-pay is the dominant funding posture because the Universal Health Insurance Authority does not currently cover specialty oncology imports of this magnitude. Families typically coordinate USD funds from relatives in the Gulf or Europe, while the patient and treating oncologist work the case in Cairo, Alexandria, or another tertiary centre.

The EDA named-patient pathway for Imdelltra

The Egyptian Drug Authority was created by Law No. 151 of 2019, with executive regulations issued by Prime Minister Decision No. 777 of 2020. EDA permits importation of unregistered medicines for a specific patient where no equivalent registered product is available locally or where the available quantity cannot meet the patient's clinical need. The pathway is

commonly referred to as Personal Importation. The application is filed through the dispensing institution's import pharmacy, typically a university hospital import desk, a private specialty oncology centre, or a licensed specialty importer in Cairo.

A complete Imdelltra application typically includes:

- A clinical justification letter from the treating medical oncologist, original, stamped, on hospital letterhead, stating the diagnosis of ES-SCLC, documentation of prior platinum-based chemotherapy and progression date, current performance status, and why Imdelltra is the appropriate next-line therapy
- The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference
- A recent prescription specifying brand name (Imdelltra), generic name (tarlatamab-dlle), and the FDA-labeled step-up cycle plan (Day 1: 1 mg IV, Day 8: 10 mg IV, Day 15: 10 mg IV, then 10 mg IV every 2 weeks)
- A patient identifier (national ID or passport copy)
- Product details: Amgen Inc. (Thousand Oaks, California), country of origin, FDA approval reference, shelf life, the 2 to 8 degree Celsius storage condition, and the kit composition (drug vial plus IV Solution Stabilizer vial, which must ship together)
- The destination dispensing facility licence number, with confirmation that the infusion centre has the capacity to monitor patients in an appropriate healthcare setting for 22 to 24 hours after the Cycle 1 Day 1 and Cycle 1 Day 8 doses
- A chain-of-custody plan describing how Imdelltra will move under unbroken 2 to 8 degree Celsius cold chain from a US specialty wholesaler through air freight to Cairo International Airport with documented temperature logging at every handoff

For Imdelltra, the clinical justification letter has unusual operational weight because the post-infusion monitoring requirement is non-trivial. The application benefits from an explicit description of how the dispensing facility will manage extended in-hospital monitoring for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), the premedication protocol (intravenous dexamethasone or equivalent plus IV hydration of at least 1 litre of normal saline before and after the first two doses), and the inpatient or observation-unit capacity for the Cycle 1 step-up doses. Routine EDA personal-import authorisations for well-documented oncology cases are typically processed in 3 to 6 week windows; complex first-time bispecific biologic imports can extend to 8 to 14 weeks. EDA reserves discretion at every step.

Where Imdelltra gets dispensed in Egypt

Imdelltra requires an adult oncology infusion centre with capacity for extended post-infusion monitoring (22 to 24 hours after the Cycle 1 Day 1 and Day 8 doses), CRS management infrastructure, and unbroken cold-chain handling for the kit. The Egyptian institutions that fit this profile include Cairo University Hospitals (Kasr Al Ainy), the oldest and largest academic hospital network in Egypt and the Middle East, with dedicated oncology and rare-disease units and an institutional import workflow; Ain Shams University Hospitals, the second major academic hospital network in Cairo with strong oncology services and routine experience with imported specialty drugs; Dar Al Fouad Hospital in 6th of October City, JCI-accredited since 2005, with active oncology and neuroscience services and over 250 bone marrow transplants of operational experience; As-Salam International Hospital in Cairo; and the Cleopatra Hospitals Group, the largest private hospital group in Egypt.

Children's Cancer Hospital Egypt 57357 is the largest pediatric oncology hospital in the world by bed count, but ES-SCLC is an adult disease and routes to adult thoracic oncology programmes rather than 57357. For families outside Cairo and Giza, the practical pattern is referral to a Cairo-based adult oncology centre with cooperation from the regional oncologist.

Real cost picture for Imdelltra in Egypt

Reserve Meds quotes patients in US dollars and accepts USD wire transfers. The Egyptian pound has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026. Quoting in USD insulates the patient from intra-case currency drift. The US wholesale acquisition cost at 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. The Amgen-published estimated annualised cost is approximately USD 781,500 per year for a patient remaining on therapy continuously.

The drug cost is the dominant line item. International cold-chain logistics from a US specialty wholesaler to Cairo International Airport typically run USD 600 to 1,500 per shipment, depending on volume and urgency. EDA permit fees and Egyptian customs charges sit on the dispensing facility's side. Inpatient or observation-unit bed costs for the 22 to 24 hour monitoring period after the Cycle 1 step-up doses, premedication, IV hydration, oncologist supervision, and ongoing performance-status and imaging assessments sit on the hospital ledger and are typically substantial in private specialty hospitals. Reserve Meds itemises the US-side drug procurement, the international logistics, and the concierge coordination fee separately on every firm quote, never bundled.

On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, and Misr Insurance each assess named-patient oncology imports case by case, typically with pre-authorisation requirements. UHIA coverage of specialty oncology imports of this magnitude is not the operating path in 2026. Cash-pay remains the dominant posture.

Typical timeline for Imdelltra in Egypt

For a routine Egyptian Imdelltra case with complete documentation, the EDA personal-import window is typically 3 to 6 weeks. Imdelltra adds two operational dimensions on top of that. First, the product is a kit (drug vial plus IVSS vial) that must ship together; partial-kit sourcing is not viable, and limited-distribution status at US specialty wholesalers can add allocation latency. Second, the biologic class extends transit timing by 2 to 3 days because of validated 2 to 8 degree Celsius packaging and continuous temperature monitoring through Cairo International Airport. A first-time import at a given Egyptian oncology centre may add 2 to 3 weeks for institutional pharmacy onboarding and CRS-protocol confirmation. Reserve Meds typically plans an initial sourcing window covering the first 2 to 3 cycles with the understanding that ongoing access is re-quoted as treatment continues.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA application and, for Imdelltra, the strongest letters consistently include: a confirmed diagnosis of extensive-stage small cell lung cancer with the supporting imaging and pathology; documentation of prior platinum-based chemotherapy regimen and progression date, per the FDA-approved second-line indication; the patient's current performance status and rationale for systemic therapy; the proposed step-up dosing plan (Day 1: 1 mg, Day 8: 10 mg, Day 15: 10 mg, then 10 mg every 2 weeks until progression or unacceptable toxicity); the premedication and IV hydration protocol per label; an explicit description of how the dispensing facility will accommodate 22 to 24 hour post-infusion monitoring after the Cycle 1 Day 1 and Day 8 doses; the post-infusion driving and machinery restriction (48 hours after each infusion); and the prescribing physician's EMS membership and Ministry of Health licence verification matched to the dispensing facility.

The treating physician retains the clinical decision and the pharmacovigilance reporting obligation through EPVC, using either the Yellow Card or CIOMS forms. Reserve Meds supplies the structured documentation template, the EPVC reference contacts, and the chain-of-custody packet. We do not write the clinical letter, do not direct dosing, and do not file adverse-event reports.

Common questions about Imdelltra in Egypt

Will Bupa Egypt, AXA Egypt, MetLife Egypt, or Allianz Egypt cover Imdelltra?

Each insurer assesses named-patient oncology imports case by case. Pre-authorisation is typically required given the unit cost. Reserve Meds supplies the documentation set; the claim filing stays with you or the dispensing hospital. Cash-pay is the default posture and many Egyptian families reimburse themselves later if coverage applies.

What is the safety profile we should monitor?

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 grade 1 or 2 and occurring during Cycle 1. Other common reactions in over 20 percent of patients included fatigue, pyrexia, dysgeusia, decreased appetite, musculoskeletal pain, constipation, anemia, and nausea. Extended post-infusion monitoring for the Cycle 1 step-up doses is mandatory.

Can my regional oncologist in the Delta or Upper Egypt manage Imdelltra?

The treating physician must have admitting privileges at a facility capable of meeting the 22 to 24 hour post-infusion monitoring requirement for the Cycle 1 doses. For most regional oncologists in the Delta or Upper Egypt the practical pattern is co-management with a Cairo or Alexandria oncology centre that holds the dispensing facility licence and the monitoring capacity. Reserve Meds confirms this is in place as part of intake clinical review.

Is there an alternative to Imdelltra?

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 bispecific T-cell engager. Comparative selection is a treating-physician decision based on patient-specific factors.

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 DeLLphi-301 trial at data cutoff was several months, but responders can remain on therapy for over a year. Reserve Meds typically quotes for an initial sourcing window (the first 2 to 3 cycles) with ongoing access re-quoted as treatment continues.

Our family is split between Cairo and the Gulf. Can you coordinate in both places?

Yes. Reserve Meds runs the patient-side coordination in Arabic where requested and the family-side coordination in English in parallel, with a single named coordinator. We support family correspondence across the UAE, Saudi Arabia, the UK, North America, and elsewhere in the Egyptian diaspora.

Where Reserve Meds fits in Imdelltra cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, do not replace EDA, and do not act as an Egyptian importer of record. What we do is orchestrate the US-side DSCSA-compliant specialty wholesaler sourcing through Amgen's authorised network, prepare validated 2 to 8 degree Celsius cold-chain logistics with continuous temperature monitoring through Cairo International Airport, and assemble the documentation kit your physician needs for the EDA Personal Importation filing. Reserve Meds requires evidence of named-patient or personal-importation authorisation, or a clear process owner at the destination authority, before US sourcing is initiated. The coordinator stays on the case from intake through the step-up cycle and into maintenance dosing, with Arabic-language patient-facing materials where the family requests them.

Next step

If a family member in Egypt has confirmed ES-SCLC with progression 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 physician and an indicative cost range in USD.

Reserved for you.
