Imdelltra access in the UAE: the MOHAP and EDE named-patient pathway

How UAE 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.

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Quick orientation

Imdelltra (tarlatamab-dlle) is the first DLL3-targeted bispecific T-cell engager approved by the US FDA, granted accelerated approval in May 2024 and converted to traditional approval in 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 the UAE as of this review. UAE oncology patients reach the medicine through the unregistered-medicine import permit administered by the Ministry of Health and Prevention (MOHAP) and, from 29 December 2025, through the Emirates Drug Establishment (EDE) portal. Reserve Meds handles the US-side specialty sourcing, the cold-chain logistics, and the documentation kit your oncologist needs. UAE is one of the first two inbound country queries logged for Imdelltra at Reserve Meds.

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Why UAE patients need Imdelltra via the named-patient pathway

The UAE federal regulatory environment is one of the most developed in the Gulf, with MOHAP holding the national drug register and the EDE assuming 44 core services from December 2025. Even with this maturity, UAE oncology patients face three structural access gaps. The drug may not yet be on the federal register at all, it may be registered for one indication but not for the patient's specific clinical situation, or it may be registered but not stocked at the specific oncology center treating the patient. For Imdelltra, the operative gap is the first: no public record of registration in MENA jurisdictions as of this module's date. The destination national authority's named-patient pathway is the legal access route.

The clinical urgency reinforces the case for the 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 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. International oncologists and hospital pharmacies routinely require US lot-level DSCSA traceability for a launch-phase biologic, which is the operating standard Reserve Meds maintains.

The MOHAP and EDE named-patient pathway for Imdelltra

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered locally is the unregistered-medicine import permit. Historically administered by MOHAP and from 29 December 2025 administered through the EDE portal at ede.gov.ae under Federal Decree-Law No. 38 of 2024, the framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (US FDA, EMA, MHRA, PMDA Japan, Health Canada) and a clinically equivalent locally registered alternative is not suitable. UAE compassionate-use provisions define compassionate use as the use of a medical product for a patient

with a serious illness or life-threatening condition outside of clinical trials when no alternative treatment options are available, and ES-SCLC after platinum failure fits that definition.

A complete Imdelltra application typically includes:

- A clinical justification letter from the treating medical oncologist (pathology-confirmed small cell lung cancer with extensive-stage disease, documentation of prior platinum-based chemotherapy with progression on or after, performance status, comorbidities, and the rationale for Imdelltra over alternatives such as topotecan or lurbinectedin)
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, matched to the dispensing hospital's emirate)
- A patient identifier (anonymised reference is preferred where the EDE submission allows)
- Full product details: Imdelltra (tarlatamab-dlle), Amgen Inc., the kit comprising the 1 mg vial and 10 mg vial plus the IV Solution Stabilizer (IVSS) vial, with the quantity reflecting the Cycle 1 step-up schedule and the planned maintenance cycles
- The destination dispensing facility (the hospital with infusion capacity and the inpatient or extended-monitoring capability the FDA label requires for the first two doses), with the pharmaceutical establishment license number and pharmacy in charge
- A chain-of-custody plan describing how Imdelltra will move from the US specialty wholesaler through the importer to the hospital pharmacy under continuous 2 to 8 degree Celsius cold chain, IATA-compliant validated shippers, and continuous temperature monitoring through to handoff

For Imdelltra, the clinical justification letter carries weight specific to the BiTE class. The strongest applications consistently document confirmation that the dispensing facility has capacity to monitor patients for 22 to 24 hours after the Cycle 1 Day 1 (1 mg) dose and the Cycle 1 Day 8 (10 mg) dose, as the FDA label requires, because of the boxed-warning risk of cytokine release syndrome and neurologic toxicity. Approval timelines for routine UAE cases are typically 5 to 15 business days. A first import of a novel-mechanism BiTE biologic with extended-monitoring requirements may extend to 4 to 6 weeks. Oncology cases at hospitals with established import-pharmacy workflow tend to move faster than first-time imports at smaller facilities.

Where Imdelltra gets dispensed in the UAE

Imdelltra requires an infusion center with adult oncology capacity, hospital-based extended monitoring (22 to 24 hours after the first two doses, then 6 to 8 hours after subsequent doses if prior infusions were tolerated), and the pharmacy infrastructure to handle a refrigerated biologic kit. The UAE institutions that fit this profile and routinely handle named-patient imports include Cleveland Clinic Abu Dhabi (the M42 group's 364-bed multispecialty hospital with adult oncology and pharmacy services accredited by the American Society of Health-System Pharmacists), Sheikh Khalifa Medical City in Abu Dhabi (the SEHA network's 586-bed JCI-accredited tertiary center managed by the Cleveland Clinic, with oncology subspecialty services), Tawam Hospital in Al Ain (the SEHA network's national oncology referral center developed in collaboration with the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, with hematology, radiation oncology, and palliative care), and American Hospital Dubai (Mayo Clinic Care Network member with oncology, hematology, and surgical oncology).

King's College Hospital London Dubai (UK-affiliated, with breast oncology), Mediclinic City Hospital in Dubai Healthcare City (urologic oncology, women's health), and the larger NMC Healthcare oncology sites can also support Imdelltra cases through in-house import pharmacy. For families in the Northern Emirates without a local center with extended-monitoring capacity, the practical pattern is to route to a Dubai or Abu Dhabi center where the treating oncologist holds privileges or where the case is co-managed with a UAE-licensed colleague.

Real cost picture for Imdelltra in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. 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 annualized cost is approximately USD 781,500 per year for a patient remaining on therapy continuously (approximately AED 2.87 million per year), before any rebates, US specialty-channel adjustments, or US-only Amgen patient assistance.

International logistics for a refrigerated biologic kit with continuous temperature monitoring and IATA-compliant validated shippers typically runs USD 800 to 1,500 (approximately AED