Datroway access in UAE: the EDE named-patient pathway

How patients in the United Arab Emirates access Datroway (datopotamab deruxtecan-dlnk) for previously treated HR-positive, HER2-negative metastatic breast cancer, an FDA-approved TROP2-directed antibody-drug conjugate not yet locally registered.

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Quick orientation

Datroway is the brand name for datopotamab deruxtecan-dlnk, a TROP2-directed antibody-drug conjugate co-developed and co-commercialised by Daiichi Sankyo and AstraZeneca. The US FDA approved Datroway on 17 January 2025 for adult patients with unresectable or metastatic HR-positive, HER2-negative (IHC 0, 1+, or 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. A second FDA accelerated approval followed in 2025 for EGFR-mutated non-small cell lung cancer after progression on EGFR-targeted therapy and platinum-based chemotherapy. As of this review date, Datroway is not on the United Arab Emirates federal drug register. A UAE-licensed medical oncologist who wants to prescribe it for a specific patient files an unregistered-medicine import permit through the Emirates Drug Establishment (EDE). Reserved for you.

Why patients in the UAE need Datroway via a named-patient pathway

HR-positive, HER2-negative metastatic breast cancer is the largest molecular subtype of advanced breast cancer worldwide. The standard treatment sequence (endocrine therapy with a CDK4/6 inhibitor, then later-line endocrine maneuvers and chemotherapy) leaves a meaningful gap when patients exhaust endocrine and chemotherapy options. Datroway adds a TROP2-directed antibody-drug conjugate option in that gap. The EMA granted Datroway marketing authorisation on 4 April 2025 for the same breast cancer indication, but in international markets outside the US and EU, ADC access typically lags by 12 to 36 months. As of this review date Datroway is not registered with the EDE or its predecessor MOHAP register, and the standard UAE distribution channels do not stock it. For a UAE patient whose disease has progressed through endocrine and chemotherapy lines and whose treating oncologist has identified Datroway as the next clinical option, the EDE named-patient pathway is the practical legal route.

Three reasons explain the volume of UAE inquiry: Datroway is not yet locally registered with the EDE, even where a regional referral pathway exists Datroway is not stocked at UAE infusion centres, and patients who try to source ADCs through unverified channels face counterfeit risk, cold-chain breaks, and no DSCSA traceability. The EDE pathway sourced through DSCSA-compliant US specialty wholesale provides a documented alternative.

The EDE named-patient pathway for Datroway

The federal pathway is the unregistered-medicine import permit. MOHAP historically administered the pathway, and from 29 December 2025 the Emirates Drug Establishment took

over 44 core services under Federal Decree-Law No. 38 of 2024, including marketing authorisations, import and export permits, pharmacovigilance oversight, and personal-use import permits. EDE filings flow through ede.gov.ae. The framework allows licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority and a clinically equivalent locally registered alternative is not suitable. Compassionate-use provisions in UAE law cover serious illness or life-threatening conditions where alternative treatment options are not available.

For a Datroway submission, the clinical justification letter centres on the metastatic breast cancer diagnosis, the receptor status, and the prior-line history. The letter typically documents the HR-positive, HER2-negative status (IHC 0, 1+, or 2+/ISH-) with the pathology report, the metastatic disease sites, the prior endocrine therapy and CDK4/6 inhibitor exposure, and the prior chemotherapy line for unresectable or metastatic disease. It records the treatment response, the progression event, and the clinician's rationale for an ADC at this point in the sequence. Where the alternative is Trodelvy (sacituzumab govitecan), another approved TROP2-ADC in the same setting, the letter notes the comparator and the reasoning for Datroway specifically (toxicity profile, clinician judgement, or patient-specific factors).

Crucially, the letter addresses the safety monitoring plan. Datroway carries a Warning and Precaution for interstitial lung disease and pneumonitis, a recognised class effect of the deruxtecan payload also seen with Enhertu (where the boxed warning appears). Severe, life-threatening, or fatal ILD/pneumonitis has been reported with Datroway. The clinician's monitoring plan documents how new or worsening pulmonary symptoms (cough, dyspnoea, fever) will be assessed, the workup triggered by any suspected ILD, and the commitment to permanently discontinue Datroway for any Grade 2 or higher ILD or pneumonitis. The plan also documents the ophthalmologic monitoring schedule for keratitis and dry eye, the antiemetic premedication regimen, and the steroid eye drop prophylaxis schedule.

The standard EDE application set follows. The treating oncologist's UAE medical licence verification is filed (MOHAP, DHA, DOH, or Sharjah Health Authority depending on practice location). The patient identifier is included anonymised where the EDE submission allows. Full product details: brand name Datroway, generic name datopotamab deruxtecan-dlnk, manufacturer Daiichi Sankyo Inc. with AstraZeneca Pharmaceuticals LP as co-commercial partner, strength (100 mg single-dose vial), quantity per cycle, intended number of cycles. The destination infusion centre name, licence number, and pharmacy in charge are listed, with a chain-of-custody plan that explicitly references continuous 2 to 8 degrees Celsius cold-chain handling through customs and into the infusion centre's bonded pharmacy.

Approval timelines for routine cases are typically 5 to 15 business days. ADCs that require pharmacy reconstitution and cold-chain handling typically fall within this band at the major tertiary oncology centres that have prior import experience. Urgent oncology cases can sometimes receive expedited review, although timelines remain at the authority's discretion and are not promised.

Where Datroway gets dispensed in the UAE

Datroway is administered exclusively as an intravenous infusion. Unreconstituted vials are stored refrigerated at 2 to 8 degrees Celsius in the original carton to protect from light. Reconstitution with sterile water for injection happens at the infusion site, with subsequent dilution in 5 percent dextrose injection. The product is incompatible with sodium chloride solutions during preparation. Direct-to-home delivery is not the model. The medicine ships cold-chain to a UAE-licensed infusion centre where the patient receives it.

The UAE institutions with adult medical oncology, infusion pharmacy capability, and prior named-patient import experience include Cleveland Clinic Abu Dhabi (M42 group, ASHP-accredited pharmacy services), Sheikh Khalifa Medical City and Tawam Hospital in the SEHA network (Tawam being the national oncology referral centre developed with Johns Hopkins Sidney Kimmel), American Hospital Dubai (Mayo Clinic Care Network), King