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

How patients in the United Arab Emirates access Enhertu (fam-trastuzumab deruxtecan-nxki) for HER2-positive, HER2-low, HER2-ultralow, HER2-mutant NSCLC, gastric, and tumour-agnostic HER2 IHC 3+ indications.

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1. Quick orientation

Enhertu is the brand name for fam-trastuzumab deruxtecan-nxki, a HER2-directed antibody-drug conjugate co-developed and co-commercialised by Daiichi Sankyo and AstraZeneca. The US Food and Drug Administration first approved Enhertu in December 2019 for HER2-positive metastatic breast cancer and has progressively expanded the label across HER2-positive second-line breast (May 2022, DESTINY-Breast03), HER2-low metastatic breast (August 2022, DESTINY-Breast04), HER2-mutant unresectable or metastatic non-small cell lung cancer (August 2022, DESTINY-Lung02), HER2-positive locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (January 2021 accelerated and subsequent regular approvals), HR-positive HER2-low and HER2-ultralow metastatic breast cancer (DESTINY-Breast06), and a tumour-agnostic accelerated approval in April 2024 for previously treated metastatic HER2 IHC 3+ solid tumours. In the UAE, Enhertu has been registered or is accessible through local agents for HER2-positive indications, but newer label expansions such as HER2-low, HER2-ultralow, HER2-mutant NSCLC, and the tumour-agnostic HER2 IHC 3+ indication routinely lag the US label. UAE patients with biopsies matching these expanded indications, or whose hospital cannot source the drug locally for any reason, reach Enhertu through the federal unregistered-medicine import permit administered by MOHAP and, from 29 December 2025, through the EDE portal. Reserved for you.

2. Why UAE patients need Enhertu via the named-patient pathway

Three structural patterns repeat in the UAE specialty oncology landscape. A drug can be registered nationally but not stocked at a particular hospital. A drug can be registered for one indication but the treating oncologist is prescribing it for another FDA-approved indication that is not yet on the local label. Or a drug can be FDA-approved but not yet registered locally at all.

Enhertu sits primarily in the second and third patterns. Enhertu has been registered or is accessible through local agents in the UAE for HER2-positive metastatic breast cancer, with regional supply through Daiichi Sankyo and AstraZeneca partners. However, indication coverage and reimbursement status vary, and HER2-low metastatic breast cancer (August 2022 FDA), HER2-ultralow (DESTINY-Breast06), HER2-mutant NSCLC (August 2022 FDA), and the tissue-agnostic HER2 IHC 3+ approval (April 2024) typically reach FDA before local registration in most international markets. The result is a patient whose biopsy returns HER2 IHC 1+ or 2+ ISH-negative (HER2-low), or HER2 IHC 3+ in a non-breast tumour, or a HER2-mutant lung adenocarcinoma, and who cannot be matched to a local stock under the older HER2-positive registration. The MOHAP and EDE named-patient pathway is the route to access in those cases.

The companion-diagnostic dimension is unusually consequential for Enhertu. Indications are HER2-status-defined: HER2 IHC and ISH/FISH for HER2-positive indications, HER2 IHC for HER2-low and HER2-ultralow breast cancer, HER2 IHC 3+ for the tumour-agnostic indication, and HER2 mutation testing (typically next-generation sequencing) for HER2-mutant NSCLC. Local or regionally approved testing is acceptable per label for the NSCLC HER2-mutation indication. UAE patients reach Enhertu only after a pathology report has assigned a specific HER2 status that matches a specific Enhertu indication, which is exactly the framing the medical-necessity narrative is built around.

3. The MOHAP and EDE named-patient pathway for Enhertu

The federal pathway for a UAE-licensed oncologist to obtain Enhertu when the medicine is not locally stocked for the prescribed indication is the unregistered-medicine import permit. The framework has historically been administered by MOHAP and is now administered through the EDE portal at ede.gov.ae as of 29 December 2025 under Federal Decree-Law No. 38 of 2024. The pathway 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 (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable.

A complete application typically includes:

- A clinical justification letter from the treating oncologist naming Enhertu, the indication, and the HER2 testing result that supports it
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location)
- An anonymised patient identifier where the EDE submission allows
- Full product details: Enhertu, fam-trastuzumab deruxtecan-nxki, 100 mg lyophilised single-dose vial, manufacturer Daiichi Sankyo, quantity sufficient for the planned cycle count
- The destination infusion center name, license number, and pharmacy in charge
- A cold-chain plan describing the 2 to 8 degrees Celsius shipment, continuous temperature monitoring, and excursion-quarantine procedure

The clinical-justification angle for Enhertu turns on companion-diagnostic documentation. The oncologist documents the HER2 testing platform, the IHC score or ISH result or HER2 mutation finding, the date of pathology, the indication being prescribed against, and the prior-line therapy and progression history. For HER2-positive metastatic breast cancer post-trastuzumab and prior trastuzumab-based regimens, DESTINY-Breast03 supports second-line use. For HER2-low metastatic breast cancer (HR-positive post-endocrine), DESTINY-Breast04 supports the indication. For HER2-mutant NSCLC, DESTINY-Lung02 supports the indication. For HER2-positive gastric or gastroesophageal junction adenocarcinoma after a prior trastuzumab regimen, the original gastric approval applies. For tumour-agnostic HER2 IHC 3+ solid tumours under accelerated approval, the April 2024 approval applies. Approval timelines for routine UAE cases are typically 5 to 15 business days. Complex first-import cases (HER2-low, HER2-ultralow, tumour-agnostic where these are first imports of the indication into the facility) can extend to 4 to 6 weeks.

4. Where Enhertu gets dispensed in the UAE

Enhertu is a cold-chain antibody-drug conjugate administered as an intravenous infusion. The dispensing requirement is a UAE-licensed hospital or specialty infusion center with cold-chain receipt capability (2 to 8 degrees Celsius vial storage), vial-level inventory controls, reconstitution capability under aseptic conditions, and infusion-cen