Enhertu access in Egypt: the EDA personal-import named-patient pathway

How patients in Egypt access Enhertu (fam-trastuzumab deruxtecan-nxki) for HER2-positive, HER2-low, HER2-mutant NSCLC, gastric, and tissue-agnostic indications, with attention to the boxed warning on interstitial lung disease and the cold-chain logistics requirement.

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

1. Quick orientation

Enhertu is the brand name for fam-trastuzumab deruxtecan-nxki, a HER2-directed antibody-drug conjugate (ADC) co-developed and co-commercialized 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 since expanded the label to second-line HER2-positive metastatic breast cancer (DESTINY-Breast03, May 2022), HER2-low metastatic breast cancer (DESTINY-Breast04, August 2022), HER2-mutant unresectable or metastatic non-small cell lung cancer (DESTINY-Lung02, August 2022), HER2-positive gastric or gastroesophageal junction adenocarcinoma after prior trastuzumab, HR-positive HER2-low and HER2-ultralow metastatic breast cancer (DESTINY-Breast06), and a tissue-agnostic accelerated approval in April 2024 for HER2 IHC 3+ solid tumors. In Egypt, some Enhertu indications may be accessible through registered local-agent supply at major specialty hospitals, but the newer HER2-low, HER2-ultralow, HER2-mutant NSCLC, and tissue-agnostic indications typically run through EDA Personal Importation under Law No. 151 of 2019. Reserved for you.

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

Egypt has one of the highest breast cancer burdens in the Middle East and North Africa, with the disease consistently ranked the most commonly diagnosed cancer among Egyptian women. Egyptian breast cancer series have repeatedly observed presentation at younger ages and at more advanced stages than is typical in Western series, which has driven sustained investment in HER2 testing infrastructure and HER2-directed therapy across the major Cairo, Giza, and Alexandria oncology centres. The Enhertu access gap in Egypt is structural and falls into two of the patterns EDA filings most commonly address: registered for a different indication, and not registered locally at all for the newest indications.

Enhertu has been registered or is accessible through local agents in the United Arab Emirates, Saudi Arabia, Kuwait, Qatar, and several other GCC markets for the older HER2-positive metastatic breast cancer and HER2-positive gastric indications. In Egypt, local-agent supply for older Enhertu indications may be available at major specialty hospitals on a stocked or imported basis, but local registration of one indication does not imply availability for all indications. 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) reach FDA before local registration in most international markets, so Egyptian patients with biopsies matching these expanded indications often cannot access the drug locally even where Enhertu is on the EDA list for HER2-positive metastatic breast cancer. The high Egyptian breast cancer prevalence translates into a meaningful number of patients with HER2-low or HER2-ultralow tumours under endocrine-line care who become Enhertu candidates after DESTINY-Breast04 and DESTINY-Breast06 data became standard of care in the US. Substitution to a HER2-positive ADC such as trastuzumab emtansine (Kadcyla) is not a clinical option for the HER2-low and tissue-agnostic indications. There is no direct ADC equivalent.

3. The EDA named-patient pathway for Enhertu

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations under Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA is a public service authority affiliated to the Prime Minister and consolidates functions previously held by the National Organization for Drug Control and Research (NODCAR), the National Organization for Research and Control of Biopharmaceuticals (NORCB), and the Ministry of Health's Central Administration of Pharmaceutical Affairs (CAPA). EDA permits the importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally, or where the available quantity of an equivalent registered product cannot meet the patient's clinical need. This is the pathway commonly referred to as Personal Importation, sometimes described in EDA correspondence as Special Access or Compassionate Use for unregistered drugs.

The standard application package for Enhertu includes the clinical justification letter from the treating medical oncologist (for breast, lung, or tissue-agnostic indications), thoracic oncologist (for NSCLC), or gastric/GI oncologist (for gastric or GEJ), on hospital letterhead, original and stamped, stating the diagnosis and stage, the indication-specific HER2 testing result (HER2 IHC and/or ISH/FISH for HER2-positive indications; HER2 IHC for HER2-low and HER2-ultralow breast cancer; HER2 IHC 3+ for the tissue-agnostic indication; local or regionally approved testing acceptable per label for the NSCLC HER2-mutation indication), prior therapies attempted and failed, and the specific reason this product is required rather than a locally available alternative; a recent prescription specifying brand name (Enhertu), generic name (fam-trastuzumab deruxtecan-nxki), strength (100 mg lyophilized powder per single-dose vial), weight-based mg/kg dosing per indication, and quantity of vials required for the planned coordination window; a patient identifier; the treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference; product details (Daiichi Sankyo Inc. as US NDA holder, AstraZeneca as joint commercialization partner, country of origin, FDA approval reference, 2 to 8 degrees Celsius storage); the destination dispensing facility licence (infusion centre with cold-chain receipt, vial-level inventory, and 2 to 8 degree Celsius storage capability); and a chain-of-custody plan with continuous temperature monitoring.

The clinical-justification angle that matters most for Enhertu is the indication-specific HER2 testing result paired with the prior-line clinical narrative. For HER2-low breast cancer, the letter cites DESTINY-Breast04 (Modi et al., NEJM 2022); for HER2-positive second-line breast cancer, DESTINY-Breast03 (Cortes et al., NEJM 2022); for HER2-mutant NSCLC, DESTINY-Lung02; for HER2-positive gastric, DESTINY-Gastric01 (Shitara et al., NEJM 2020); and for tissue-agnostic HER2 IHC 3+ solid tumours, the April 2024 accelerated approval. Routine EDA personal-import authorisations for well-documented oncology cases are typically processed in a 3 to 6 week window once a complete package is submitted. Biologics with cold-chain sensitivity and off-label indications can extend to 8 to 14 weeks or longer where supplementary documentation is requested. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

4. Where Enhertu gets dispensed in Egypt

Enhertu is a biologic ADC supplied as a lyophilized powder in a single-dose 100 mg vial for reconstitution and intravenous infusion. Unopened vials must be stored refrigerated at 2 to 8 degrees Celsius in the original carton, protected from light, and must not be frozen or shaken. Reconstitution uses 5 mL of Sterile Water for Injection per 100 mg vial to yield a 20 mg/mL solution, then diluted into a 5 percent dextrose infusion bag (saline is not compatible) and administered intravenously. The first infusion is given over 90 minutes; subsequent infusions may be given over 30 minutes if tolerated. The dispensing requirement in Egypt is therefore not a routine outpatient pharmacy but a hospital infusion centre with validated 2 to 8 degree Celsius storage, oncology pharmacy reconstitution capability, and infusion infrastructure.

Egyptian oncology programmes with established named-patient import workflow and infusion infrastructure capable of receiving and administering Enhertu include Cairo University Hospitals (Kasr Al Ainy), with a Drug Information Center, an institutional import workflow, and full medical-oncology infusion capacity; Ain Shams University Hospitals, with strong oncology and hepatology services and routine experience with imported specialty cold-chain drugs; Dar Al Fouad Hospital in 6th of October City, Giza, a JCI-accredited private super-specialty hospital with the 1999 Cleveland Clinic cooperation

agreement, active oncology, neuroscience, and organ transplantation services, and cold-chain infusion capability; As-Salam International Hospital in Cairo; and the Cleopatra Hospitals Group, the largest private hospital group in Egypt with oncology, cardiology, and surgical infrastructure across multiple Cairo facilities. For patients outside Cairo, Giza, and Alexandria, the practical path is for the case to be co-managed with one of the institutions above or routed through a Cairo-based licensed specialty importer that delivers to the regional infusion centre with the cold-chain documentation maintained end-to-end.

5. Real cost picture for Enhertu in Egypt

Reserve Meds quotes Enhertu cases in USD and accepts USD wire transfers. The EGP 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 case from intra-case currency drift. Three line items frame the economics.

First, drug cost. Public pricing references list the Enhertu 100 mg vial at approximately USD 2,400 to USD 3,200, with US wholesale acquisition cost at the higher end of that band. A single weight-based dose typically requires multiple vials, so per-dose cost depends on patient weight and indication-specific mg/kg. For a representative 70 kg patient at 5.4 mg/kg, a single dose is approximately 378 mg (rounded up to four 100 mg vials), placing per-dose drug cost in the approximately USD 10,000 to USD 13,000 range at WAC and USD 16,000 to USD 19,000 range at common all-in specialty-pharmacy acquisition once handling and channel margin are layered in. Gastric dosing at 6.4 mg/kg pushes per-dose cost higher. Per-course cost scales with duration of response, which can extend many months. At the May 2026 EGP/USD rate, a per-dose drug cost in the USD 10,000 to USD 19,000 range corresponds to approximately EGP 520,000 to EGP 1.0 million per dose.

Second, international cold-chain logistics. Enhertu is a strict 2 to 8 degree Celsius product. Qualified temperature-controlled packaging, continuous temperature monitoring, and customs handling that accommodates active or passive cold chain push international logistics from the US source to Cairo International Airport into the USD 700 to USD 1,500 range (approximately EGP 37,000 to EGP 80,000) per shipment, with insurance riders. Excursions outside 2 to 8 degrees Celsius require quarantine pending stability assessment.

Third, Egyptian regulatory documentation handling fees on the dispensing facility side, and the Reserve Meds concierge fee, itemised on the firm quote and never bundled. On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, MedGulf Egypt, Orient Takaful, and Royal Insurance each assess named-patient imports case by case. The Universal Health Insurance Authority (UHIA) does not currently cover most specialty imports. Cash-pay is the dominant posture. Many Egyptian families coordinate USD funds via relatives in the Gulf, the UK, or North America.

6. Typical timeline for Enhertu in Egypt

Enhertu is a 2 to 8 degree Celsius biologic with cold-chain sensitivity, which extends the routine timeline relative to ambient products. End-to-end, a typical Enhertu case in Egypt runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 5 to 10 days for the treating oncologist's team to assemble the personal-import application with the indication-specific HER2 testing report, the prior-line clinical narrative, and the dispensing facility documentation; 3 to 6 weeks for routine EDA review, with cold-chain biologics and newer indications (HER2-low, tissue-agnostic, HER2-mutant NSCLC) sometimes extending to 8 to 14 weeks where supplementary documentation is requested mid-review; 5 to 7 days for US sourcing through the Daiichi Sankyo and AstraZeneca authorized specialty distribution channel, qualified cold-chain shipper preparation, and continuous-monitor courier shipment to Cairo International Airport; 1 to 3 days for customs clearance under the EDA authorisation with cold-chain handling maintained end-to-end; and final verification at the hospital infusion centre with vial integrity and temperature-log check before reconstitution. Because Enhertu is dosed once every three weeks until disease progression or unacceptable toxicity, with duration of response extending many months across indications, Reserve Meds plans repeat-shipment cadence from the first case.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA personal-import application for Enhertu. The treating Egyptian oncologist documents the indication-specific diagnosis: for HER2-positive metastatic breast cancer, HER2 IHC 3+ or ISH/FISH-positive status, the line of therapy, and prior anti-HER2 regimens; for HER2-low or HER2-ultralow metastatic breast cancer (HR-positive), HER2 IHC 1+ or 2+/ISH-negative or ultralow status, prior endocrine therapy lines, and the rationale framed against DESTINY-Breast04 and DESTINY-Breast06; for HER2-mutant unresectable or metastatic NSCLC, the HER2 mutation result with the laboratory reference; for HER2-positive locally advanced or metastatic gastric or GEJ adenocarcinoma, the HER2 status and the prior trastuzumab regimen; and for the tissue-agnostic indication, HER2 IHC 3+ status and prior systemic therapy lines, framed against the April 2024 accelerated approval. The letter states the indication-specific dosing regimen: 5.4 mg/kg IV every three weeks for breast (HER2-positive, HER2-low, HER2-ultralow), HER2-mutant NSCLC, and tissue-agnostic HER2 IHC 3+ indications; 6.4 mg/kg IV every three weeks for HER2-positive gastric or GEJ. The first infusion is given over 90 minutes; subsequent infusions may be given over 30 minutes if tolerated. Premedication with antiemetics is recommended given the moderate-to-high emetogenic potential.

The monitoring plan addresses the boxed warning for interstitial lung disease (ILD) and pneumonitis, including fatal cases, and embryo-fetal toxicity. ILD has been reported in approximately 12 percent of patients treated at 5.4 mg/kg with fatal outcomes in approximately 0.9 percent. The letter documents baseline and periodic chest CT surveillance, patient counselling to report new respiratory symptoms immediately, CBC monitoring for cytopenias, LVEF assessment for cardiac function, and pregnancy status confirmation with contraception counselling. The letter is co-filed with the physician's EMS membership and Ministry of Health licence reference, the dispensing facility licence with documented 2 to 8 degree Celsius storage and infusion capability, the requested vial count and quantity (Enhertu 100 mg lyophilized powder, single-dose vials, vials sufficient for the planned coordination window per patient weight and indication), and the chain-of-custody plan from the US Daiichi Sankyo and AstraZeneca authorized specialty distribution channel through to the Egyptian infusion centre. Pharmacovigilance reporting through the Egyptian Pharmacovigilance Center (EPVC) using Yellow Card or CIOMS forms applies for the duration of therapy and is the prescribing physician's obligation, with ILD events receiving expedited reporting.

8. Common questions about Enhertu in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover the cost? Each insurer assesses named-patient imports case by case. Some plans reimburse a percentage when the drug treats a covered indication. We supply the documentation an insurer needs to assess. The claim filing remains with the patient or the hospital. Cash-pay is the default posture.

Does UHIA cover specialty imports like Enhertu? Not as a general rule. The Universal Health Insurance rollout under Law No. 2 of 2018 is phased through to 2032, with Cairo, Giza, and Qalyubia in the final phase. For most named-patient specialty imports in 2026, UHIA coverage is not the funding path.

I have HER2-low metastatic breast cancer. Is the pathway different from HER2-positive? The pathway is the same. The clinical-justification letter cites the HER2-low IHC result (1+ or 2+/ISH-negative) and the DESTINY-Breast04 and DESTINY-Breast06 data, and the dosing regimen is 5.4 mg/kg IV every three weeks. The fact that local registration for HER2-low typically lags HER2-positive registration is precisely what makes the personal-import route the operative path for these patients.

What is the interstitial lung disease boxed warning and how is it managed? Enhertu carries a boxed warning for ILD and pneumonitis, including fatal cases. ILD has been reported in approximately 12 percent of patients at 5.4 mg/kg with fatal outcomes in approximately 0.9 percent. Baseline and periodic chest CT surveillance is mandated; patients are counselled to report new respiratory symptoms immediately. Dose modifications for ILD are detailed in the prescribing information. The treating oncologist owns this monitoring.

Is there a competitor or alternative? Trastuzumab emtansine (Kadcyla) was the prior standard-of-care HER2 ADC in second-line metastatic breast cancer; DESTINY-Breast03 established Enhertu's superiority in that setting. There is no direct ADC equivalent for the HER2-low and tissue-agnostic indications. The treating oncologist makes the regimen call.

Can the family receive Enhertu at home or at an outpatient pharmacy? No. Enhertu is given as an IV infusion in a clinic or infusion centre under medical supervision, with reconstitution by the oncology pharmacy and 2 to 8 degree Celsius storage of unopened vials. The destination dispensing facility in Egypt is a hospital infusion centre, not an outpatient pharmacy or the patient's home.

9. Where Reserve Meds fits in Enhertu cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating oncologist, EDA, your infusion centre, or your insurer, and we do not act as an importer of record in Egypt. What we do for an Enhertu case is verify eligibility within 24 to 48 hours; supply your oncologist's team with a documentation kit referencing the FDA prescribing information, the indication-specific DESTINY trial citation, the HER2 testing requirement, and the EDA Personal Importation application format; align the US-side sourcing through the Daiichi Sankyo and AstraZeneca authorized specialty distribution channel with the Egyptian infusion centre; coordinate the qualified cold-chain courier shipment under continuous temperature monitoring and chain-of-custody documentation to Cairo International Airport; and provide a single named coordinator across the case, in Arabic on the patient side and English on the family side where the family is split across the diaspora. The cold-chain requirement and the boxed-warning monitoring stack make oncology-centre-of-care continuity in Egypt a precondition for case acceptance. Reserve Meds coordinates supply only and does not provide clinical oversight. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Egyptian oncologist has confirmed an FDA-approved Enhertu indication (HER2-positive, HER2-low, HER2-ultralow, HER2-mutant NSCLC, gastric, or tissue-agnostic HER2 IHC 3+) and recommends fam-trastuzumab deruxtecan-nxki, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

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Last medically reviewed: 2026-05-12.