Enhertu access in Saudi Arabia: the SFDA Personal Importation Program

How patients in the Kingdom of Saudi Arabia 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 Kingdom of Saudi Arabia, 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. Saudi patients with biopsies matching these expanded indications, or whose hospital cannot source the drug locally for any reason, reach Enhertu through the SFDA Personal Importation Program (PIP). Reserved for you.

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

Three structural patterns repeat in the Kingdom's specialty oncology landscape. A drug can be registered with SFDA but not stocked at the treating hospital on the day the patient needs it (stocking decisions sit with the institution, not with SFDA). 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 Kingdom 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 Kingdom 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 SFDA PIP 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. Saudi 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. Saudi Vision 2030's Health Sector Transformation Program is also expanding diagnostic capacity in oncology genomics, which surfaces new patients who

need drugs FDA-approved but not registered locally for the specific indication, reinforcing the role of the named-patient framework.

3. The SFDA Personal Importation Program for Enhertu

The SFDA Personal Importation Program allows a Kingdom-licensed physician to request import of a specific medicine for a specific named 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 for the patient. The framework explicitly contemplates oncology and rare-disease therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector. SFDA increasingly routes named-patient activity through its Ghad digital platform alongside the agency's English portal at sfda.gov.sa.

A complete PIP application for Enhertu includes the clinical justification letter from the treating oncologist; the treating physician's licensing verification through the Saudi Commission for Health Specialties (SCFHS) in medical oncology or relevant specialty; the patient identifier in the format SFDA requires for the named-patient case file; full product details (Enhertu, fam-trastuzumab deruxtecan-nxki, 100 mg lyophilised single-dose vial, manufacturer Daiichi Sankyo, requested quantity sufficient for the planned cycle count); the destination dispensing facility license; and a chain-of-custody plan from the US point of release through international transit (with cold-chain validation, continuous temperature monitoring, and an excursion-quarantine procedure documented) to the receiving Saudi infusion-center pharmacy.

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 SFDA cases run 10 to 21 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 6 to 10 weeks.

4. Where Enhertu gets dispensed in Saudi Arabia

Enhertu is a cold-chain antibody-drug conjugate administered as an intravenous infusion. The dispensing requirement is a Kingdom-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-center capacity to deliver a 90-minute first infusion followed by 30-minute subsequent infusions where tolerated. The boxed warning for interstitial lung disease (ILD) and pneumonitis additionally requires baseline and on-treatment chest CT imaging access, so the dispensing site is paired with imaging and pulmonology support.

Kingdom institutions with oncology services and infusion-center capability that handle named-patient cold-chain biologics include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah, with tertiary and quaternary referral oncology, breast oncology, thoracic oncology, gastrointestinal oncology, and a national role in HER2-driven disease; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network in Riyadh and Jeddah; King Saud University Medical City (KSUMC); Dr. Sulaiman Al Habib Medical Group (HMG), the largest private hospital network in the Kingdom with multiple Riyadh, Jeddah, and Eastern Province facilities and routine PIP activity through their import pharmacy operations; Saudi German Hospital; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. For oncologists at smaller hospitals without an internal import pharmacy, the typical pattern is to route the case through a Riyadh- or Jeddah-based SFDA-licensed specialty importer that handles the PIP filing and delivers the medicine to the infusion-center pharmacy under cold-chain custody.

5. Real cost picture for Enhertu in Saudi Arabia

The Saudi riyal is pegged at approximately 3.75 SAR to 1 USD, which makes the dollar-denominated US wholesale acquisition cost the principal driver of the case economics. Three line items frame the cost.

First, drug cost. The US wholesale acquisition cost for Enhertu is set per 100 mg single-dose vial. Public pricing references list the 100 mg vial at approximately USD 2,400 to USD 3,200 (roughly SAR 9,000 to SAR 12,000), with WAC at the higher end. 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 (roughly SAR 37,500 to SAR 48,750) and USD 16,000 to USD 19,000 range at common all-in specialty-pharmacy acquisition. The gastric and gastroesophageal junction indication dosing at 6.4 mg/kg pushes per-dose cost higher. Per-course cost scales with duration of response, which can extend many months.

Second, international logistics. Enhertu is a strict 2 to 8 degrees Celsius product. Shipments require qualified temperature-controlled packaging, continuous temperature monitoring, and customs handling that accommodates active or passive cold chain. International logistics for a cold-chain shipment to the Kingdom typically runs USD 800 to USD 2,500 (approximately SAR 3,000 to SAR 9,375) depending on city of delivery (Riyadh and Jeddah are the operational hubs), urgency window, and active versus passive packaging.

Third, regulatory and coordination. SFDA documentation handling fees and Reserve Meds' concierge fee are itemised separately. On the insurance side, Bupa Arabia, Tawuniya (The Company for Cooperative Insurance), and MedGulf Arabia handle named-patient imports case by case, with several requiring pre-authorisation with the clinical justification letter attached. The Council of Cooperative Health Insurance (CCHI) governs how these insurers structure their plans. Cash-pay is the default operating posture, with reimbursement sought after delivery if the plan permits. Reserve Meds quotes an indicative range based on the initial intake, then a transparent firm quote with each line item shown separately.

6. Typical timeline for Enhertu in Saudi Arabia

The SFDA timeline for routine PIP cases runs 10 to 21 business days. Enhertu is a cold-chain biologic, which adds 2 to 3 days to the transit window relative to ambient products. End-to-end, a typical Enhertu case in the Kingdom runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 7 days for the treating oncologist and the dispensing hospital pharmacy or specialty importer to assemble the application with HER2 testing documentation; 10 to 21 business days for SFDA review (longer for first import of an expanded-indication use such as HER2-low or tumour-agnostic into a given facility, where 6 to 10 weeks is plausible); 4 to 6 days for US sourcing through Daiichi Sankyo and AstraZeneca specialty distribution channels, release documentation, and qualified cold-chain shipment with continuous temperature monitoring; 1 to 2 days for Saudi customs clearance under the PIP permit; and final receipt-temperature verification and release at the infusion-center pharmacy. Subsequent cycles every three weeks are planned for repeat shipments from the first case.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA PIP application. The treating Kingdom oncologist documents the patient's diagnosis (HER2-positive metastatic breast cancer, HER2-low or HER2-ultralow HR-positive metastatic breast cancer post-endocrine therapy, HER2-mutant unresectable or metastatic NSCLC, HER2-positive locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, or HER2 IHC 3+ previously treated metastatic solid tumour); states the HER2 companion-diagnostic result with explicit reference to the testing platform (HER2 IHC, ISH/FISH, HER2 next-generation sequencing for the NSCLC indication, with the result, date, and laboratory); itemises prior lines of therapy and progression documentation; explains why a locally registered alternative is not suitable (for HER2-low, HER2-ultralow, HER2-mutant NSCLC, and the tumour-agnostic indication, this is straightforward because no equivalent ADC is locally registered for these specific indications); states the planned dosing regimen (5.4 mg/kg IV every three weeks for breast and lung indications and the tumour-agnostic indication; 6.4 mg/kg IV every three weeks for gastric and gastroesophageal junction adenocarcinoma; first infusion over 90 minutes, subsequent over 30 minutes where tolerated;

premedication with antiemetics; treatment until disease progression or unacceptable toxicity); and describes the monitoring plan, with particular emphasis on the boxed warning for interstitial lung disease and pneumonitis.

The monitoring stack includes baseline and periodic chest CT surveillance for ILD with prompt evaluation of new respiratory symptoms; CBC monitoring for cytopenias; LVEF assessment for cardiac function; pregnancy status confirmation given the boxed warning for embryo-fetal toxicity; and counselling on infection and respiratory warning signs. The letter is co-filed with the physician's SCFHS license verification, the infusion-center license number, the requested vial count and cycle plan, and the cold-chain plan for receipt at the dispensing site. Post-import, the treating physician and dispensing pharmacy commit to adverse-event reporting through the SFDA National Pharmacovigilance Center for the full course of therapy.

8. Common questions about Enhertu in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Enhertu? Each plan handles named-patient imports case by case. Some reimburse fully when the medicine appears on the insurer's formulary even when the local hospital pharmacy did not have it stocked for the prescribed indication; some reimburse a percentage; many require pre-authorisation with the clinical justification letter attached. The CCHI governs plan structure. We do not promise coverage from any insurer.

Will my Ministry of Health-employed oncologist's letter be sufficient? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications. Private-sector oncologists at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Is HER2 companion-diagnostic testing available in the Kingdom? Yes. Major Kingdom oncology pathology services at KFSH&RC, KAMC, and reference laboratories aligned with HMG and the larger private networks run HER2 IHC, ISH/FISH, and HER2 next-generation sequencing on certified platforms. HER2-low and HER2-ultralow IHC scoring requires a pathologist trained in the updated DESTINY-Breast04 and DESTINY-Breast06 scoring conventions; the testing laboratory is identified in the PIP filing.

What is the safety profile I should know about? Enhertu carries a boxed warning for interstitial lung disease and pneumonitis, including fatal cases, and for 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. Other common adverse reactions include nausea, fatigue, alopecia, vomiting, neutropenia, anemia, thrombocytopenia, decreased appetite, diarrhoea, and left ventricular dysfunction. Patients are counselled to report any new cough, dyspnoea, fever, or other new respiratory symptoms immediately.

Is Enhertu self-administered? No. Enhertu is given as an IV infusion in a clinic or infusion center under medical supervision. The first infusion is over 90 minutes; subsequent infusions may be over 30 minutes if tolerated.

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. Trastuzumab plus chemotherapy regimens remain alternatives in some lines and indications. There is no direct ADC equivalent for the HER2-low, HER2-ultralow, HER2-mutant NSCLC, or tumour-agnostic HER2 IHC 3+ indications. The treating oncologist makes the selection; Reserve Meds does not endorse one regimen over another.

9. Where Reserve Meds fits in Enhertu cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating oncologist, SFDA, the dispensing hospital or infusion-center pharmacy, your imaging team, or your insurer. What we do for an Enhertu case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the FDA prescribing information, the indication-specific dosing, the HER2 companion-diagnostic requirements, and the ILD monitoring stack; align US-side sourcing through Daiichi Sankyo and AstraZeneca specialty distribution channels under DSCSA-compliant chain-of-custody; coordinate cold-chain shipment with a qualified specialty 3PL under continuous temperature monitoring; and provide a single named Patient Concierge Coordinator across the case. The cold-chain requirement and the boxed-

warning monitoring stack make oncology-center-of-care continuity in the Kingdom 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 Kingdom oncologist has identified an Enhertu indication that matches your HER2 testing and recommends therapy, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›
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