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Enhertu access in Pakistan: the DRAP Special Permission pathway

How patients in Pakistan access Enhertu (fam-trastuzumab deruxtecan-nxki) for HER2-directed breast, gastric, lung and solid tumor indications.

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 that pairs the HER2-targeting monoclonal antibody trastuzumab with a deruxtecan topoisomerase I inhibitor payload via a cleavable linker. The US Food and Drug Administration first approved Enhertu in December 2019 for adults with unresectable or metastatic HER2-positive breast cancer after two or more prior anti-HER2 regimens, with subsequent label expansions for second-line HER2-positive metastatic breast cancer, HER2-low and HER2-ultralow metastatic breast cancer, HER2-mutant non-small cell lung cancer, HER2-positive gastric or gastroesophageal junction adenocarcinoma, and a tissue-agnostic HER2 IHC 3+ solid-tumor accelerated approval in April 2024. Daiichi Sankyo holds the New Drug Application; AstraZeneca is the joint commercialisation partner. In Pakistan, where breast cancer burden is among the highest in Asia, Enhertu's local availability does not consistently track the expanding US label. Pakistani patients whose treating oncologist has confirmed a label-eligible HER2 indication reach Enhertu through the Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import No Objection Certificate. Reserved for you.

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

Three patterns of access gap apply across Pakistan: a drug is on the DRAP register but the patient's hospital pharmacy does not have it on hand; a drug is registered for one indication but the physician is prescribing it for another FDA-approved indication that the local distributor does not import; or a drug is FDA-approved but the manufacturer has not yet completed DRAP registration in the form or for the indication the patient needs. Enhertu touches all three patterns, depending on the indication. HER2-positive metastatic breast and gastric indications have varying local availability through Daiichi Sankyo and AstraZeneca's distribution partners in the region, while HER2-low metastatic breast cancer (FDA-approved August 2022), HER2-ultralow under DESTINY-Breast06, HER2-mutant NSCLC, and the tissue-agnostic HER2 IHC 3+ approval (April 2024) typically reach FDA before any local Pakistani availability and route through the named-patient pathway.

Three structural reasons converge in Pakistan. First, indication lag. The expanding US label reaches patients whose biopsies match the newer HER2-low, HER2-ultralow, HER2-mutant NSCLC, and tissue-agnostic indications well before equivalent local availability is established. Second, supply lag and allocation: even where a local registration exists for the older indications, on-shelf supply at hospital pharmacies in Karachi and Lahore has not always kept pace with demand after FDA expansion approvals, and local agents allocate carefully with tertiary cancer centres triaging in-system patients first. Third, the underlying disease burden. Breast cancer incidence in Pakistan is documented among the highest in Asia, with a median age at diagnosis approximately a decade younger than in Western populations, and Pakistani families with HER2-positive disease frequently exhaust standard regimens and reach the ADC second-line and later settings that the Enhertu label addresses. The cash-pay framing is unavoidable: most Pakistani health plans do not reimburse imported specialty oncology drugs, and families routinely fund care through pooled household resources including overseas remittances.

3. The DRAP Special Permission pathway for Enhertu

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA<) Division's Import and Export Section, with Drug Registration Board oversight for new product registration matters. For unregistered medicines or unstocked indications required by a specific patient, DRAP issues a Special Permission, also known as the Personal Use Import No Objection Certificate (NOC). The framework covers Personal Use Import by an individual patient on physician prescription and Special Permission for Import of Unregistered Therapeutic Goods by hospitals or institutions, filed through DRAP's Online Import and Export System (OIES) electronic portal.

A complete DRAP application for Enhertu includes the clinical justification letter from the treating medical oncologist (diagnosis with site of disease, HER2 status by IHC and/or ISH/FISH or HER2-mutant NSCLC documentation, prior therapies attempted, reason this specific drug is required); the treating physician's PMDC license verification with specialist registration in medical oncology; the patient identifier (CNIC for adults, B-Form for minors, passport for foreign nationals); full product details (Enhertu, fam-trastuzumab deruxtecan-nxki, Daiichi Sankyo, 100 mg single-dose vial for reconstitution, requested vial count per the indication-specific dose calculation); the destination dispensing facility license including infusion-centre capability; the manufacturer or authorised distributor letter confirming legitimate supply chain sourcing; and a chain-of-custody plan for the strict 2 to 8 degrees Celsius cold-chain shipment.

The clinical justification angle for Enhertu turns on indication-matched HER2 biomarker confirmation. The treating oncologist documents the patient's HER2 status with explicit reference to the appropriate companion diagnostic for the prescribed indication (HER2 IHC and/or ISH/FISH for HER2-positive breast, gastric, and tissue-agnostic indications; HER2 IHC for HER2-low and HER2-ultralow breast cancer; HER2 IHC 3+ for the tissue-agnostic indication; HER2 mutation documentation for the NSCLC indication, with local or regionally approved testing acceptable per label); the prior-line treatment history establishing eligibility for the requested line of therapy; the planned indication-specific dosing (5.4 mg/kg every three weeks for breast, lung, and tissue-agnostic indications; 6.4 mg/kg every three weeks for gastric or GEJ adenocarcinoma); and a detailed ILD/pneumonitis surveillance plan because of the boxed warning. Routine DRAP personal-use cases typically clear in four to eight we