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# Enhertu access in India: the CDSCO Rule 36 named-patient pathway

How patients in India access Enhertu (fam-trastuzumab deruxtecan-nxki) for HER2-positive, HER2-low, HER2-mutant, and HER2 IHC 3+ tumors when local stocking or indication coverage falls short.

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

## 1. Quick orientation

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Enhertu is the brand name for fam-trastuzumab deruxtecan-nxki, a HER2-directed antibody-drug conjugate (ADC) co-developed 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 expanded the label across multiple indications, including HER2-low metastatic breast cancer (DESTINY-Breast04), HER2-mutant non-small cell lung cancer (DESTINY-Lung02), HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma, and a tissue-agnostic accelerated approval in April 2024 for previously treated metastatic HER2 IHC 3+ solid tumors. The WHO Model List of Essential Medicines 2023 includes trastuzumab deruxtecan for HER2-positive metastatic breast cancer. In India, access has historically run through CDSCO pathways for indications and supply that lag US approvals. Patients reach Enhertu through Rule 36 of the Drugs and Cosmetics Rules 1945, with the office of the Drugs Controller General of India (DCGI) issuing Form 12B against a complete Form 12A application. Reserved for you.

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

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India has the largest tertiary specialty hospital network of any Reserve Meds priority country, and Daiichi Sankyo and AstraZeneca have stated approvals in 35 or more countries for non-small cell lung cancer and 45 or more countries for gastric cancer. Yet for Indian patients, three patterns of access gap show up repeatedly: registered but not stocked, registered for a different indication, or supply allocated to in-system institutional patients first.

Indication lag drives the first wave of Indian Rule 36 demand. HER2-low metastatic breast cancer (FDA August 2022 under DESTINY-Breast04), HER2-ultralow under DESTINY-Breast06, HER2-mutant unresectable or metastatic NSCLC, and the tissue-agnostic HER2 IHC 3+ accelerated approval in April 2024 reach FDA before they are registered locally. A patient with biopsy-confirmed HER2-low or HER2-mutant disease cannot rely on the locally registered HER2-positive label to cover them. Supply lag is the second wave: even where Enhertu is approved through CDSCO for one indication, on-shelf supply at hospital pharmacies in Mumbai, Delhi, Bangalore, Chennai, and Hyderabad has not always kept pace with demand following expansion approvals, and tertiary cancer centres triage to in-system patients first.

The clinical case is anchored by the WHO Essential Medicines List 2023 inclusion of trastuzumab deruxtecan for HER2-positive metastatic breast cancer, which gives Indian oncologists a defensible reference point in the Form 12A clinical justification letter. There is no direct ADC equivalent for HER2-low and tissue-agnostic indications. Once the HER2 IHC, ISH or FISH, or HER2-mutation status is documented per the indication-specific companion diagnostic, the medical-necessity narrative writes itself.

## 3. The CDSCO Rule 36 named-patient pathway for Enhertu

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The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of a small quantity of a drug for the exclusive personal use of a named patient, with the legal basis sitting under Section 10 of the Drugs and Cosmetics Act 1940.

Form 12A is the application for a permit, made under the second proviso to Rule 36. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) whose National Medical Commission (NMC) registration number appears on the prescription, with the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

For institutional Compassionate Use of the drug in indications not approved for marketing in India at all (HER2-low, HER2-ultralow, HER2-mutant NSCLC, tissue-agnostic HER2 IHC 3+), the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route is used where the drug is approved by a recognised reference authority such as the FDA for a life-threatening condition. AIIMS and Tata Memorial Centre have established workflow for this pathway.

A complete CDSCO application for Enhertu typically includes:

- A clinical justification letter (diagnosis, HER2 biomarker status per indication, prior anti-HER2 lines tried and failed, the specific reason this product is required)
- The treating oncologist's NMC registration number and state-council registration where required
- A patient identifier and supporting medical records
- Product details: Enhertu, fam-trastuzumab deruxtecan-nxki, Daiichi Sankyo / AstraZeneca, 100 mg single-dose vial of lyophilized powder for reconstitution, vial count sufficient for the planned treatment cycle
- The dispensing facility's drug licence (hospital infusion pharmacy with cold-chain capability, or specialty importer's wholesale licence)
- A chain-of-custody plan from the US specialty distributor through a cold-chain 3PL to the dispensing pharmacy in India, with continuous temperature monitoring documentation

The clinical-justification angle that matters most for Enhertu is indication-specific biomarker confirmation. For HER2-positive disease, the letter cites HER2 IHC and/or ISH/FISH. For HER2-low and HER2-ultralow breast cancer, HER2 IHC. For HER2-mutant NSCLC, locally or regionally approved HER2-mutation testing per label. For the tissue-agnostic indication, HER2 IHC 3+. CDSCO published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications. In practice, families and hospitals plan for a two to four week window from physician decision to first infusion, because the bulk of the elapsed time is upstream documentation assembly and downstream cold-chain logistics rather than the regulator's stamp.

#### **4. Where Enhertu gets dispensed in India**

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