

Enhertu

Bahrain · access guide

How to access Enhertu from Bahrain, the named-patient import pathway, 2026

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

A Bahraini patient with HER2-positive and HER2-low breast cancer, HER2-positive gastric cancer, HER2-mutant non-small cell lung cancer, and HER2-expressing solid tumors per the FDA tumor-agnostic indication may receive a prescription for Enhertu (trastuzumab deruxtecan) from their treating oncologist. Enhertu is FDA-approved in the United States and manufactured by Daiichi Sankyo and AstraZeneca. It is a HER2-directed antibody-drug conjugate administered by intravenous infusion. Local availability of Enhertu in Bahrain can be inconsistent: the drug may not be on every specialty pharmacy's standing formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through NHRA remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

The clinical situation

Enhertu is a HER2-directed antibody-drug conjugate. Mechanism: a HER2-directed antibody conjugated to a topoisomerase I inhibitor (DXd) by a cleavable tetrapeptide-based linker. Dosing: 5.4 mg/kg by intravenous infusion every three weeks for breast cancer, 6.4 mg/kg for gastric cancer, per FDA labeling. Baseline workup per FDA labeling includes complete blood count with differential, liver function tests, baseline left ventricular ejection fraction, and high-resolution chest imaging for interstitial lung disease screening. The FDA boxed warning covers interstitial lung disease and embryo-fetal toxicity. Other important warnings include interstitial lung disease and pneumonitis (including fatal cases), left ventricular dysfunction, neutropenia, and embryo-fetal toxicity. Your oncologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Enhertu legally importable into Bahrain?

Yes, through the Bahrain National Health Regulatory Authority (NHRA) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. Bahrain has an established pathway for specialty medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The NHRA named-patient route allows a Bahraini-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility. Applications are typically filed through the dispensing institution's import pharmacy on the physician's behalf, with approval issued on a per-patient, per-cycle quantity basis.

How the pathway works, step by step

1. **Consultation with your treating oncologist.** The prescribing decision is clinical. Your oncologist documents the indication, prior therapies where relevant, and rationale for Enhertu.
2. **Baseline screening.** Complete blood count with differential, liver function tests, baseline left ventricular ejection fraction, and high-resolution chest imaging for interstitial lung disease screening are confirmed and documented.
3. **NHRA named-patient application.** Your oncologist or the facility's import pharmacy files the application with clinical rationale, patient reference, product strength, quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from Daiichi Sankyo and AstraZeneca's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Enhertu requires refrigerated transport at 2 to 8 degrees Celsius. Shipments include temperature-monitored packaging with continuous loggers and tamper-evident seals.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your oncologist initiates therapy.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, prior therapies where relevant, and Enhertu as the indicated next step
- Verification of their Bahraini medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above)
- The planned dosing regimen (5.4 mg/kg by intravenous infusion every three weeks for breast cancer, 6.4 mg/kg for gastric cancer, per FDA labeling)
- A monitoring plan covering ILD monitoring plan, LVEF baseline, and HER2 IHC or ISH result

Reserve Meds provides a physician documentation kit tailored for HER2-directed antibody-drug conjugate therapies, including the templates NHRA reviewers commonly request.

Typical costs and indicative timing

Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for a single 3-week cycle (weight-dependent) of Enhertu sits in an indicative 2026 band of approximately USD 15,000 to 21,000. International logistics, NHRA documentation handling, cold-chain shipping, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 2 to 5 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the dosing schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Enhertu specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for NHRA review, including HER2-directed antibody-drug conjugate class templates.
- **Cold-chain logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility with continuous temperature loggers.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating oncologist, and dispensing sits with the licensed Bahraini pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Bahrain? Yes, when executed through the NHRA named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at Bahraini tertiary centers.

What about the boxed warning? The FDA boxed warning on Enhertu covers interstitial lung disease and embryo-fetal toxicity. Your oncologist performs the risk-benefit assessment, schedules monitoring, and counsels the patient per labeling. Reserve Meds does not make that clinical judgement, your physician does.

Will my private health insurance cover this? Cash-pay is the default posture. Some Bahraini private insurers reimburse named-patient imports on a case-by-case basis. We supply documentation for your submission but do not process insurance claims.

How does cold-chain affect timing? Enhertu ships refrigerated. We use validated packaging with continuous temperature monitoring, and arrival temperature data is logged on every shipment.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Bahraini tertiary centers (King Hamad University Hospital, Salmaniya Medical Complex, and the Bahrain Oncology Center) have encountered. Our documentation kit is written for first-time applicants and tracks what NHRA reviewers commonly ask for.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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