## Herceptin

Kuwait · access guide

# How to access Herceptin from Kuwait, the named-patient import pathway, 2026

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

A Kuwaiti patient with HER2-overexpressing breast cancer in the adjuvant and metastatic settings, and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma may receive a prescription for Herceptin (trastuzumab) from their treating oncologist. Herceptin is FDA-approved in the United States and manufactured by Genentech (Roche). It is a humanised HER2-directed monoclonal antibody administered by intravenous infusion. Local availability of Herceptin in Kuwait 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 KMOH 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

Herceptin is a humanised HER2-directed monoclonal antibody. Mechanism: a humanised IgG1 monoclonal antibody that binds the extracellular domain of HER2 and inhibits downstream signaling. Dosing: loading and maintenance dosing by intravenous infusion every 1 or 3 weeks per FDA labeling; subcutaneous Herceptin Hylecta is an alternative. Baseline workup per FDA labeling includes baseline left ventricular ejection fraction by echocardiogram or MUGA, complete blood count, and HER2 testing confirmation (IHC 3+ or ISH amplified). The FDA boxed warning covers cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Other important warnings include cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Your oncologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

## Is Herceptin legally importable into Kuwait?

Yes, through the Kuwait Kuwait Ministry of Health (KMOH) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Kuwait 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 KMOH named-patient route allows a Kuwaiti-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 Herceptin.
2. **Baseline screening.** Baseline left ventricular ejection fraction by echocardiogram or MUGA, complete blood count, and HER2 testing confirmation (IHC 3+ or ISH amplified) are confirmed and documented.
3. **KMOH 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 Genentech (Roche)'s authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Herceptin 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 Herceptin as the indicated next step
- Verification of their Kuwaiti 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 (loading and maintenance dosing by intravenous infusion every 1 or 3 weeks per FDA labeling; subcutaneous Herceptin Hylecta is an alternative)
- A monitoring plan covering HER2 confirmation, LVEF baseline, and biosimilar-versus-originator preference note

Reserve Meds provides a physician documentation kit tailored for HER2-directed monoclonal antibody therapies, including the templates KMOH 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 every-3-week cycle (weight-dependent; biosimilars often lower) of Herceptin sits in an indicative 2026 band of approximately USD 4,000 to 6,500. International logistics, KMOH 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.

## Why Herceptin still appears in Kuwait NPP cases despite local registration

Trastuzumab is locally registered in Kuwait and broadly available through MoH-coordinated oncology centers and the major private hospitals. Most Kuwait HER2-positive breast cancer patients receive trastuzumab through standard local channels, Kuwait Cancer Control Center, Hadi Clinic, Royale Hayat, Dar Al Shifa, and the larger MoH oncology services. So why does Herceptin appear in our cross-border catalogue for Kuwait at all?

The NPP route arises in specific circumstances: when an expatriate patient prefers the originator Herceptin over a locally-available biosimilar for continuity reasons (they started therapy on the originator in the US or Europe), when a specific lot or formulation is not currently in local stock, or when the patient is bridging between Kuwait care and care in another country and wants documentation continuity. These are minority case profiles relative to the broader Kuwait HER2-positive patient population, but they do occur regularly enough to maintain the access guide.

The HER2 status confirmation (IHC 3+ or FISH-amplified) is a non-negotiable gate regardless of sourcing route. Funding for Kuwait NPP trastuzumab cases is typically self-pay, since local-registered alternatives are reimbursable through standard channels, the family is choosing to pay for the specific originator product. KDFC's NPP framework will scrutinize the clinical justification more carefully when a locally-registered alternative exists; we document the rationale with the prescribing oncologist before submission.

Cardiac monitoring (echocardiogram or MUGA at baseline and every 3 months on therapy) per labeling is standard practice at Kuwait oncology centers. The oncologist handles this; we handle sourcing and shipping logistics.

### More questions, specific to this case

**If trastuzumab biosimilars are available in Kuwait, why source the originator?**

Some patients started therapy on the originator product (e.g., in the US or Europe) and prefer continuity. Some prescribers prefer originator for specific clinical scenarios. This is a clinical and patient-preference decision, not a Reserve Meds recommendation.

**Does the NPP framework cover trastuzumab when it is locally available?**

KDFC's NPP framework is generally reserved for unregistered drugs. For locally-registered products like trastuzumab, the request needs explicit justification for the originator product specifically. We document the justification with the prescriber.

**Should I switch from biosimilar to originator mid-course?**

That is a clinical decision your oncologist makes. The two are bioequivalent per FDA and EMA evidence and switching is not routinely recommended without clinical reason.

### *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.

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