Herceptin

Pakistan · access guide

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

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

A Pakistani 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 Pakistan 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 DRAP 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 Pakistan?

Yes, through the Drug Regulatory Authority of Pakistan (DRAP) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. Pakistan 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 DRAP named-patient route allows a Pakistani-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. **DRAP 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 Pakistani 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 DRAP 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, DRAP 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.

How Pakistan cases for originator Herceptin typically come together

Trastuzumab is registered in Pakistan and available through DRAP-approved local channels including the originator and multiple biosimilars (some manufactured in-country). Most HER2-positive breast cancer patients in Pakistan receive trastuzumab through standard oncology channels, Aga Khan University Hospital, Shaukat Khanum Memorial Cancer Hospital (Lahore, Karachi, Peshawar), Liaquat National Hospital, and the larger CMH oncology services.

The NPP route from outside Pakistan arises for specific scenarios: when an expatriate is on continuity from US or EU therapy and prefers the originator brand, when supply gaps temporarily affect local availability, or when a patient is coordinating care across multiple countries and wants documentation consistency. These are a small fraction of the total Pakistan HER2-positive patient population, but the operational pattern is consistent enough to warrant this guide.

HER2 confirmation (IHC 3+ or FISH-amplified) validated at AKUH lab, SKMCH lab, or a reference pathology center is the gate. Funding is typically self-pay for originator-via-NPP, since local-registered alternatives are reimbursable through Sehat Sahulat or private insurance. The cost differential matters: originator via NPP, with international logistics, is materially more expensive than local biosimilar. We share the all-in figure at intake.

We coordinate the sourcing; the oncologist handles cardiac monitoring (echocardiogram or MUGA per labeling, every 3 months) and the standard chemotherapy or endocrine regimen. Customs clearance through Karachi or Lahore typically requires DRAP no-objection certificate paperwork attached to the shipment; we handle that documentation.

More questions, specific to this case

Why pursue Herceptin via cross-border NPP when local biosimilars are available?

Patient or prescriber preference for originator continuity. The choice is clinical or personal; we don't recommend one direction or the other.

Is the cost of originator Herceptin via NPP higher than local trastuzumab?

Yes typically. The patient is paying for originator brand and international logistics. We provide the all-in figure at intake.

Does the Pakistani oncologist need any additional approval to administer NPP-sourced Herceptin?

Standard clinical responsibility. The NPP framework documentation covers regulatory clearance. Administration is per standard practice.

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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