Datroway access in Pakistan

A TROP2-directed antibody-drug conjugate for previously treated HR+, HER2-negative metastatic breast cancer, reached through the Drug Regulatory Authority of Pakistan Special Permission pathway.

Quick orientation

Datroway (datopotamab deruxtecan-dlnk) is a TROP2-directed antibody-drug conjugate co-developed and co-commercialised by Daiichi Sankyo and AstraZeneca. The US FDA granted approval on January 17, 2025 for adults with unresectable or metastatic hormone receptor-positive (HR+), HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. A second FDA approval in 2025 covers EGFR-mutated non-small cell lung cancer after progression on EGFR-targeted therapy and platinum-based chemotherapy. Datroway is administered exclusively as an intravenous infusion every three weeks. For Pakistani families whose treating medical oncologist has documented progression after endocrine and chemotherapy lines in HR+/HER2- metastatic breast cancer, Datroway is not yet registered with DRAP and is reached lawfully through the Drug Regulatory Authority of Pakistan Special Permission for Personal Use Import (the NOC), filed through the OIES portal. Reserve Meds coordinates the US specialty wholesaler sourcing, the cold-chain logistics, the regulatory documentation kit, and a single named coordinator across the case. Clinical decisions stay with your oncologist. Reserved for you.

Why patients in Pakistan need Datroway via the named-patient pathway

HR+, HER2-negative metastatic breast cancer is the largest molecular subtype of advanced breast cancer worldwide. The standard treatment sequence (endocrine therapy plus a CDK4/6 inhibitor, then later-line endocrine maneuvers and chemotherapy) leaves a meaningful gap when patients exhaust endocrine and chemotherapy options. Datroway adds a TROP2-directed ADC option in that gap. In Pakistan, as of the module date, Datroway is not on the DRAP register, and Daiichi Sankyo and AstraZeneca have not announced a Pakistani filing. Even where regional ADC availability exists through Gulf affiliates, in-country stocking has not begun. Pakistani families whose oncologist seeks an ADC option therefore reach for Datroway through a named-patient channel.

The pattern in Pakistan typically combines two features. First, the drug is not registered locally, so the hospital pharmacy cannot stock it through ordinary channels. Second, attempts to source ADCs through unverified channels carry counterfeit risk, cold-chain breaks, and no DSCSA traceability, which are unacceptable for a temperature-sensitive deruxtecan biologic. Reserve Meds coordinates DSCSA-compliant US sourcing with documented chain-of-custody, end-to-end cold-chain validation, and Pakistan-specific DRAP named-patient documentation tuned to the dispensing institution. Daiichi Sankyo and AstraZeneca US patient support programs are US-only and do not extend to international cases.

The DRAP named-patient pathway for Datroway

DRAP regulates the import of unregistered medicines through the QA&LT Division's Import and Export Section. For unregistered medicines required by a specific named patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Institutional applications for hospital-administered infusion products are typically filed by the dispensing hospital's import pharmacy through the Online Import and Export System (OIES). Where the treating oncologist is at a smaller institution without import pharmacy infrastructure, the practical route is to partner with a Karachi-based or Lahore-based DRAP-licensed specialty importer.

The application package for a Datroway case typically includes the clinical justification letter from the treating medical oncologist on hospital letterhead, the oncologist's PMDC licence verification, the patient identifier (CNIC for adult patients or passport for foreign nationals), product details (Datroway brand name, datopotamab deruxtecan-dlnk INN, manufacturer of record Daiichi Sankyo Inc. and AstraZeneca Pharmaceuticals LP co-commercial, 100 mg single-dose vial, requested quantity calculated from patient body weight at 6 mg/kg per cycle with the 540 mg per-dose cap for patients weighing 90 kg or more), the destination dispensing facility licence including infusion capability and oncology day unit infrastructure, a US specialty wholesaler letter confirming DSCSA-compliant sourcing through the authorised Daiichi and AstraZeneca channel, and a chain-of-custody plan from the US source through international shipment with continuous 2 to 8 degrees Celsius temperature monitoring to the dispensing facility.

The clinical-justification angle specific to Datroway is the prior-line documentation, the molecular profile, and the ILD risk acknowledgment. The letter typically documents the metastatic breast cancer diagnosis with HR+ and HER2-negative status (IHC 0, IHC 1+, or IHC 2+/ISH-), the prior endocrine-based therapy (named medicines and outcomes, typically including a CDK4/6 inhibitor combination) and the prior chemotherapy for unresectable or metastatic disease with documented progression. The TROPION-Breast01 evidence base (median PFS 6.9 months versus 4.9 months on investigator's choice chemotherapy, HR 0.63, confirmed ORR 36 percent versus 23 percent) supports the clinical rationale. The dosing plan is stated (6 mg/kg IV every 21 days, first infusion over 90 minutes, subsequent infusions over 30 minutes if tolerated). Premedication is specified (multi-drug antiemetic regimen with a corticosteroid, a 5-HT3 antagonist, with or without an NK1 antagonist; steroid eye drops starting on the day of each infusion and continuing for several days afterward). The letter explicitly references the FDA prescribing information's Warning and Precaution for interstitial lung disease and pneumonitis (a recognised class effect of the deruxtecan payload), the requirement to hold Datroway for any suspected ILD pending workup, and the requirement to permanently discontinue for any Grade 2 or higher ILD or pneumonitis, with patient counseling on this risk completed.

Routine DRAP personal-use cases typically clear in four to eight weeks from a complete submission. Cold-chain biologic cases for newly launched oncology ADCs can extend to ten to sixteen weeks at first authorisation. Reserve Meds plans on the longer end and treats any faster turnaround as upside. DRAP reserves discretion at every step.

Where Datroway gets dispensed in Pakistan

Datroway is a 2 to 8 degrees Celsius cold-chain biologic that requires an institutional infusion setting with hospital pharmacy reconstitution and IV bag preparation capability, oncology day unit infrastructure for the 90-minute first infusion and subsequent 30-minute infusions,

ophthalmologic monitoring access for the dry eye and keratitis ocular surface signals, oral hygiene and stomatitis management, ILD surveillance capability with prompt access to chest imaging, and the wholesale capacity to manage the embryo-fetal toxicity counseling and contraception requirement. The dispensing-facility shortlist is therefore narrow.

The Pakistani institutions that handle DRAP named-patient imports as an established workflow and have oncology day unit infrastructure for cold-chain biologics include Aga Khan University Hospital in Karachi (the Department of Oncology with eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology, with the 24/7 institutional pharmacy and temperature-controlled storage), Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore (Pakistan's flagship cancer hospital with outpatient and inpatient pharmacy services and a long track record of cold-chain oncology biologic handling, and a strong direct line into the institutional importation pathway), the Indus Hospital and Health Network in Karachi with tertiary oncology, Liaquat National Hospital in Karachi, and the Combined Military Hospitals network with tertiary capacity at CMH Rawalpindi and CMH Lahore. SKMCH&RC is the natural fit for many Datroway cases given its institutional history of negotiating directly with multinational manufacturers and its tertiary oncology pharmacy capability. For families whose treating oncologist is at a smaller institution, the typical route is to coordinate with one of the above centers as the dispensing facility while the treating oncologist retains clinical oversight.

Real cost picture for Datroway in Pakistan

Reserve Meds quotes Pakistani cases in USD and accepts USD wire transfers from any USD-accessible source. The transparent cost build for a Datroway case has three line items.

First, the underlying US drug cost. Datroway is sold by 100 mg single-dose vial. Publicly available pricing references indicate vial pricing in the approximate range of USD 4,800 to 5,000 per 100 mg vial. For a typical 70 to 80 kg patient at 6 mg/kg (roughly 4 to 5 vials per infusion), per-infusion drug cost is in the approximate range of USD 20,000 to 25,000 at US wholesale acquisition cost. A typical 6-cycle course is therefore in the approximate range of USD 120,000 to 150,000 at US WAC before any rebates or international layering. Acquisition cost for hospitals and channels may differ. Second, international cold-chain logistics from US specialty wholesaler to Karachi, Lahore, or Islamabad with continuous 2 to 8 degrees Celsius temperature monitoring and validated qualified shipper, which typically runs USD 800 to USD 1,500 per shipment. Third, regulatory documentation handling at the Pakistani end, the Reserve Meds concierge fee, and the institutional infusion administration cost (charged separately by the dispensing hospital and not flowing through Reserve Meds).

Currency context. The Pakistani Rupee traded near PKR 278 to 280 per USD in early May 2026, with annual CPI inflation at 10.9 percent in April 2026. Quoting in USD protects the family from PKR volatility. Many Pakistani families fund specialty oncology by pooling resources across overseas relatives in the Gulf, the UK, the US, and Canada. On the insurer side, Jubilee General's Personal HealthCare and Adamjee Health Insurance cover in-hospital chemotherapy and radiotherapy in some formularies, but specialty imports of FDA-approved-but-not-locally-registered ADCs are typically outside formulary. Some plans assess case-by-case. Sehat Sahulat's Rs. 1,000,000 per family per year ceiling does not stretch to cover a multi-cycle ADC course. The default is cash-pay.

Typical timeline for Datroway in Pakistan

End to end, a routine Datroway case at a tertiary cancer center with established DRAP cold-chain workflow typically clears in seven to fourteen weeks from intake to first infusion. The DRAP OIES review for a newly launched ADC takes six to twelve weeks, the US specialty wholesaler intake adds five to ten business days, and validated cold-chain international air freight plus FBR Customs clearance at Karachi, Lahore, or Islamabad adds four to seven days because of the qualified shipper qualification, temperature data logger configuration, and cold-chain customs documentation. The cold-chain leg adds two to three days versus an ambient shipment. After the first authorised import, subsequent cycle shipments on the rolling 21-day cadence can be planned tighter because the precedent file and the dispensing hospital workflow are established. Continuity of supply is the operational priority because treatment continues until disease progression or unacceptable toxicity, with median exposure of 6 to 7 cycles in the registration trials and durable responders remaining longer.

What your physician needs to provide

The cornerstone document is the clinical justification letter, original and stamped on hospital letterhead, signed by the treating medical oncologist under their active PMDC licence. For Datroway, the letter typically covers the unresectable or metastatic HR+ HER2-negative breast cancer diagnosis with explicit HER2 status documentation (IHC 0, IHC 1+, or IHC 2+/ISH- per the label), the prior endocrine-based therapy with named medicines and outcomes (typically including a CDK4/6 inhibitor combination) and the prior chemotherapy with documented progression, and the clinical rationale for a TROP2-directed antibody-drug conjugate referencing the TROPION-Breast01 evidence base.

The dosing plan is stated (6 mg/kg IV every 21 days, first infusion over 90 minutes, subsequent infusions over 30 minutes if tolerated, with a maximum dose cap of 540 mg for patients weighing 90 kg or more). Premedication is specified (multi-drug antiemetic regimen with a corticosteroid, a 5-HT3 antagonist, with or without an NK1 antagonist; steroid eye drops starting on the day of each infusion). The monitoring plan covers the FDA label's Warning and Precaution for ILD and pneumonitis with the hold-for-suspected-ILD pending workup and permanent-discontinuation-for-Grade-2-or-higher-ILD criteria called out explicitly, ophthalmologic exams at baseline and recurrently for ocular surface toxicity (dry eye, keratitis), oral hygiene counseling for stomatitis, CBC and LFT monitoring, and the embryo-fetal toxicity warning with the contraception requirement during and after treatment. Dose-modification criteria reference the first reduction to 4 mg/kg, second reduction to 3 mg/kg, and permanent discontinuation thereafter for stomatitis, ocular toxicity, and other adverse reactions. PMDC-licensed medical oncologists at tertiary cancer centers have signing authority on Pakistan Personal Use Import applications.

Common questions about Datroway in Pakistan

Will Jubilee, Adamjee, EFU, or State Life cover Datroway?
Jubilee's Personal HealthCare and Adamjee Health Insurance cover in-hospital chemotherapy in their formularies, but specialty imports of FDA-approved-but-not-locally-registered ADCs are typically outside formulary. Some plans assess case-by-case where metastatic HR+/HER2- breast cancer with progression on prior endocrine and chemotherapy is documented. Reserve Meds supplies the documentation a family or hospital needs to file a claim. The realistic default is cash-pay.

How does Sehat Sahulat interact with this?
The Rs. 1,000,000 per family per year ceiling does not stretch to cover the cost of a multi-cycle Datroway course. Families who qualify for Sehat Sahulat can still use it for hospitalisation, supportive care, and procedures while Datroway procurement runs cash-pay in parallel.

Why Datroway versus Trodelvy (sacituzumab govitecan)?
The two TROP2 ADCs share the target but use different payloads (deruxtecan in Datroway, SN-38 in Trodelvy), different linkers, and have different toxicity profiles. Trodelvy is approved in HR+/HER2- metastatic breast cancer after endocrine therapy and at least two prior chemotherapies. The selection between Datroway, Trodelvy, and chemotherapy is a treating oncologist decision based on patient-specific factors including ILD risk, ocular history, and prior chemotherapy exposure. Reserve Meds does not make this choice; we coordinate access once your oncologist has prescribed.

What is the ILD risk we need to understand?
The FDA prescribing information for Datroway includes a Warning and Precaution for interstitial lung disease and pneumonitis, a recognised class effect of the deruxtecan payload also seen with Enhertu (which carries this as a Boxed Warning). Severe, life-threatening, or fatal ILD/pneumonitis has been reported with Datroway. Clinicians monitor for new or worsening pulmonary symptoms (cough, dyspnea, fever), hold Datroway for any suspected ILD pending workup, and permanently discontinue for any Grade 2 or higher ILD or pneumonitis. Patient counseling on this risk is part of the consent before starting therapy. The Pakistani dispensing institution must have prompt access to chest imaging and pulmonology consultation.

Can my family member receive Datroway at home?
No. Datroway is an intravenous infusion that requires administration in a qualified infusion setting with appropriate monitoring capability, including infusion reaction management and the ability to escalate care if respiratory or ocular symptoms emerge.

How long will my relative stay on Datroway?
Treatment continues until disease progression or unacceptable toxicity. There is no fixed course duration. Median exposure in the registration trials was approximately 6 to 7 cycles, though responders frequently remained on therapy longer. Your oncologist makes the duration decision.

Where Reserve Meds fits in Datroway cases

Reserve Meds is a US-based concierge coordinator. We do not replace your medical oncologist, we do not replace DRAP, we do not replace your dispensing institution or the in-country importer where one is involved. For a Datroway case in Pakistan, we orchestrate the DSCSA-compliant US specialty wholesale procurement through the authorised Daiichi and AstraZeneca channel with full serial traceability, prepare the documentation kit your oncologist needs for the DRAP Special Permission filing through the OIES portal (including the molecular profile, the prior-line documentation, the dosing and premedication plan, and the explicit ILD risk acknowledgment), coordinate validated 2 to 8 degrees Celsius cold-chain international shipping with continuous temperature monitoring through Karachi, Lahore, or Islamabad airport, and stay with the case through cycle-by-cycle re-supply under a single named coordinator. Reserve Meds maintains documented named-patient access pathways for Datroway in Saudi Arabia, the UAE, and India in the country cell pages; Pakistan joins that pattern. SKMCH&RC is a natural fit for many cases given its long-standing institutional capability with international oncology supply. Clinical decisions remain with your oncologist. Regulatory authority remains DRAP. Dispensing and infusion administration remain with the licensed Pakistani institution.

Next step

If your family is exploring Datroway for an adult relative whose oncologist has documented unresectable or metastatic HR+ HER2-negative breast cancer with progression on prior endocrine-based therapy and chemotherapy, and the receiving Pakistani institution has cold-chain biologic and oncology day-unit infrastructure plus prompt chest imaging access for ILD surveillance, the next step is to join the waitlist. We will confirm eligibility and case fit within 24 to 48 hours, send a documentation kit to your treating oncologist in English with Urdu-language family-facing summaries where requested, and align with your dispensing institution or a Karachi or Lahore-based DRAP-licensed importer on the OIES filing.

Reserved for you.

Related

- Datroway drug overview
- Pakistan country guide
- DRAP Personal Use Import pathway
- Datroway in Saudi Arabia
- Datroway in the UAE
- Datroway in India
- Breast cancer condition page

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›
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