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

How adults in India with previously treated HR+/HER2- metastatic breast cancer legally obtain Datroway (datopotamab deruxtecan-dlnk) from US-source supply, with validated 2 to 8 degree Celsius cold-chain handling and interstitial-lung-disease readiness built into the case plan.

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

### Quick orientation

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Datroway (datopotamab deruxtecan-dlnk) is a TROP2-directed antibody-drug conjugate co-developed and co-commercialized by Daiichi Sankyo and AstraZeneca. The US Food and Drug Administration approved Datroway on 17 January 2025 for adults with unresectable or metastatic hormone receptor-positive (HR+), HER2-negative breast cancer (IHC 0, IHC 1+, or IHC 2+/ISH-negative) who have received prior endocrine-based therapy and chemotherapy in the metastatic setting. A second FDA approval followed in 2025 for EGFR-mutated non-small cell lung cancer after progression on or after EGFR-targeted therapy and platinum-based chemotherapy. There is no public record of Datroway registration with the Central Drugs Standard Control Organization (CDSCO) as of this review. Indian patients reach the medicine through the CDSCO personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI), or through the institutional Compassionate Use route at hospitals like AIIMS New Delhi and Tata Memorial Centre Mumbai. Reserve Meds coordinates US specialty-wholesaler sourcing through the Daiichi/AstraZeneca authorised channel, validated 2 to 8 degree Celsius cold-chain logistics, and the documentation kit your medical oncologist needs to file.

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### Why patients in India need Datroway via the named-patient pathway

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India's breast-oncology depth is real. The National Cancer Grid anchored by Tata Memorial Centre Mumbai coordinates breast-cancer standard-of-care across more than 250 institutions. AIIMS New Delhi runs a high-volume breast unit. Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis Memorial Research Institute Gurgaon, Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, Christian Medical College (CMC) Vellore, and Manipal Hospitals Bangalore run accredited breast-oncology programmes with chemotherapy day-care suites and inpatient capacity. CDK4/6 inhibitors plus aromatase inhibitors are standard first-line; later-line endocrine and chemotherapy options follow. What is missing on local formularies is a TROP2-directed antibody-drug conjugate. Datroway is not registered with CDSCO as of this review; Trodelvy (sacituzumab govitecan), the other approved TROP2 ADC, has its own registration trajectory. Personal importation under Rule 36 is the legal route for Datroway.

The clinical case for reaching across the border is sequencing-driven. HR+/HER2-negative metastatic breast cancer is the largest molecular subtype worldwide. The standard sequence

(endocrine therapy plus a CDK4/6 inhibitor, later-line endocrine maneuvers, then chemotherapy) leaves a real gap when endocrine and chemotherapy options are exhausted. Datroway's TROPION-Breast01 data (median PFS 6.9 versus 4.9 months, hazard ratio 0.63 against investigator's choice chemotherapy) put it squarely in that gap. Indian families dealing with progression after endocrine plus chemotherapy reach for Datroway because the in-country alternatives at that point in the sequence are limited.

## **The CDSCO Rule 36 named-patient pathway for Datroway**

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The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application for the permit. 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) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application; for a once-every-three-week intravenous biologic this typically accommodates multiple cycles per filing.

For institutional Compassionate Use of drugs not approved for marketing in India at all, 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. Metastatic breast cancer that has progressed on prior endocrine and chemotherapy fits the life-threatening condition framing. AIIMS, Tata Memorial Centre, and other public-sector tertiary cancer centres have established Compassionate Use workflow.

For Datroway specifically, the clinical-justification angle in the Form 12A filing is the prior-line documentation and the ILD risk acknowledgment. The strongest applications consistently document: pathology-confirmed invasive breast cancer with the molecular subtype evidence (hormone receptor positive by ER and PR immunohistochemistry; HER2 negative by IHC 0, IHC 1+, or IHC 2+/ISH-negative); imaging-confirmed unresectable or metastatic disease; the prior treatment sequence (endocrine therapy with or without CDK4/6 inhibitor, and at least one prior chemotherapy in the metastatic setting), each line with dates, regimen, response, and reason for discontinuation; the proposed dosing plan following the FDA-labeled schedule (6 mg/kg intravenous infusion once every three weeks in 21-day cycles, with a 540 mg cap for patients weighing 90 kg or more; first infusion over 90 minutes, subsequent infusions over 30 minutes if tolerated); the required premedication regimen (corticosteroid, 5-HT3 antagonist with or without NK1 antagonist for nausea control; prophylactic steroid eye drops starting the day of each infusion); and an explicit acknowledgement of the ILD/pneumonitis warning and the institutional monitoring plan. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where documentation is complete; cold-chain biologic imports at an institution that has not previously stocked a deruxtecan-based ADC may run longer for institutional pharmacy review.

## **Where Datroway gets dispensed in India**

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Datroway is an intravenous biologic requiring a hospital infusion suite with cold-chain handling capacity, pharmacy reconstitution capability with sterile water for injection followed by dilution in 5 percent dextrose (the product is incompatible with sodium chloride), infusion-reaction management readiness, and ophthalmologic access for the ocular-toxicity surveillance the label

requires. The dispensing facility must hold a valid drug licence. The Indian institutions that fit this profile and routinely handle named-patient oncology imports include AIIMS New Delhi, Tata Memorial Centre Mumbai (autonomous institution under the Department of Atomic Energy, India's oldest and largest cancer institute, anchor of the National Cancer Grid), Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata, with dedicated international patient services and JCI plus NABH accreditation), Fortis Memorial Research Institute Gurgaon and Mulund Mumbai, Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, CMC Vellore, and Manipal Hospitals Bangalore.

For Datroway, the ILD monitoring capability is the gating institutional requirement. The label mandates permanent discontinuation for any Grade 2 or higher ILD or pneumonitis, which means the receiving institution needs imaging access, pulmonologist consultation availability, and a documented hold-pending-workup protocol. We will not coordinate Datroway delivery to a facility that cannot deliver this. For patients in smaller cities, the practical pattern is to route the infusions to a tertiary breast-oncology centre rather than to a local clinic.

## **Real cost picture for Datroway in India**

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Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. US wholesale acquisition cost for Datroway is published by 100 mg single-dose vial, with reported vial pricing in the approximate range of USD 4,800 to 5,000. Per-infusion cost scales with patient body weight: at 6 mg/kg for a typical 60 to 80 kg Indian patient, four to five vials per infusion put per-cycle drug cost in the approximate range of USD 19,000 to 25,000. A typical six-cycle course at US WAC therefore falls in the approximate range of USD 115,000 to 150,000 before any rebates, US-channel adjustments, or US-only patient assistance. At the prevailing USD/INR rate, this converts to approximately INR 10.8 to 14.1 crore over a six-cycle course; longer-duration responders will exceed this range proportionately.

International validated 2 to 8 degree Celsius cold-chain shipping for the every-three-week cadence typically runs USD 800 to 1,500 (approximately INR 75,000 to 1.4 lakh) per shipment depending on city of destination, urgency window, and whether multiple cycles are consolidated. CDSCO permit fees are nominal. India's Union Budget 2026-27 expanded customs-duty exemption on a set of named cancer medicines; the specific HSN code and exemption status of each Datroway shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5 percent. The dispensing hospital's infusion fees, the premedication regimen, the ophthalmologic exams, and supportive care sit on the hospital's side of the ledger. Reserve Meds itemises the US-side procurement, the cold-chain logistics, and the concierge coordination fee separately on every firm quote.

None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Niva Bupa) reimburse a Rule 36 personal import of an unregistered oncology biologic as a standard line item. CGHS provides for life-saving anti-cancer medicines that are not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case, with stricter constraints on drugs not approved by DCGI. The Daiichi and AstraZeneca US patient support programs are US-only. Cash-pay is the operating default.

## **Typical timeline for Datroway in India**

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For a routine Indian Datroway case at an established breast-oncology institution, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing, per the regulator's published guidance. The cold-chain biologic class adds two to three days to

international transit windows compared with ambient products. Validated 2 to 8 degree Celsius shipping is rated for 72 to 120 hours, which dictates route selection and customs-clearance timing at Delhi, Mumbai, Bengaluru, Chennai, or Hyderabad airports. A first-time Datroway import at an institution that has not previously stocked a deruxtecan-based ADC may add two to four weeks for institutional pharmacy onboarding and ILD-readiness review. End-to-end, families typically plan for three to six weeks from oncologist decision to Cycle 1 Day 1. Because Datroway is dosed every three weeks until progression or unacceptable toxicity, Reserve Meds quotes an initial sourcing window (typically the first two to three cycles) and re-quotes ongoing access as treatment continues.

## **What your physician needs to provide**

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The clinical justification letter is the cornerstone of the Form 12A filing. For Datroway, the strongest letters consistently include: pathology-confirmed invasive breast cancer with hormone-receptor and HER2 status (specifying IHC 0, IHC 1+, or IHC 2+/ISH-negative); imaging-confirmed unresectable or metastatic disease with the relevant staging documentation; the documented prior treatment sequence with dates, regimens (endocrine therapy, CDK4/6 inhibitor where used, at least one prior chemotherapy in the metastatic setting), response observed, and reason for discontinuation; the proposed dosing plan following the FDA-labeled schedule (6 mg/kg intravenous infusion once every three weeks, 540 mg cap at body weight 90 kg or more, first infusion over 90 minutes, subsequent infusions over 30 minutes if tolerated); the premedication regimen (corticosteroid, 5-HT3 antagonist with or without NK1 antagonist before each infusion, and prophylactic steroid eye drops starting the day of each infusion); the monitoring plan covering baseline and recurrent ophthalmologic exams, oral hygiene counselling for stomatitis, CBC and LFTs, embryo-fetal toxicity counselling with effective contraception during and after treatment, and an explicit ILD and pneumonitis surveillance plan with the discontinuation criterion (permanent discontinuation for any Grade 2 or higher ILD/pneumonitis) acknowledged; and the prescribing oncologist's NMC registration number.

The patient identifier, the dispensing institution's drug licence, the chain-of-custody plan from the US specialty wholesaler to the Indian hospital pharmacy, and the cold-chain handling plan complete the file. The treating oncologist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation. Reserve Meds includes the PvPI reference in the documentation kit.

## **Common questions about Datroway in India**

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### **What is the safety profile we should be aware of?**

The most common adverse reactions in the registration trials (incidence 20 percent or higher) were stomatitis, nausea, fatigue, decreased leukocytes, decreased calcium, alopecia, decreased lymphocytes, decreased hemoglobin, constipation, decreased neutrophils, dry eye, vomiting, increased ALT, keratitis, increased AST, and increased alkaline phosphatase. Ocular surface toxicity (dry eye, keratitis) is a Datroway-specific signal that requires ophthalmologic monitoring and prophylactic steroid eye drops. The FDA prescribing information also includes a Warning and Precaution for interstitial lung disease and pneumonitis, a recognised class effect of the deruxtecan payload; this is a Warning and Precaution, not a Boxed Warning. Severe, life-threatening, or fatal ILD/pneumonitis has been reported with Datroway. Permanent discontinuation is required for any Grade 2 or higher ILD/pneumonitis.

## **Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Datroway?**

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered oncology biologic as a standard line item. Some plans have considered case-by-case reimbursement for advanced oncology indications with documented prior-line failure. Reserve Meds provides the itemised documentation that lets the insurer evaluate. Cash-pay is the operating default.

## **Is there a competitor or alternative?**

The closest direct comparator is Trodelvy (sacituzumab govitecan), the other approved TROP2-ADC, which is approved in HR+/HER2-negative metastatic breast cancer after endocrine therapy and at least two prior chemotherapies. The two ADCs share the TROP2 target but use different payloads (deruxtecan in Datroway, SN-38 in Trodelvy), different linkers, and have different toxicity profiles. Enhertu (trastuzumab deruxtecan) is an option in HER2-low and HER2-ultralow disease but targets HER2 rather than TROP2. The selection between Datroway, Trodelvy, and chemotherapy is the treating oncologist's clinical decision.

## **Can Datroway be administered at home?**

No. Datroway is an intravenous infusion that requires a qualified infusion setting with infusion-reaction management, ophthalmologic surveillance access, and the ability to escalate if respiratory symptoms emerge. Home infusion is not an acceptable delivery model.

## **Will my MoH-affiliated or government-medical-college oncologist's letter be sufficient?**

Yes. Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. Oncologists at AIIMS, Tata Memorial, government medical colleges, and state-run tertiary hospitals routinely sign these letters. Private-sector oncologists at Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal also have signing authority subject to their institutional drug licence and ILD-readiness capacity.

## **What is the typical course duration?**

Treatment continues every three weeks until disease progression or unacceptable toxicity. There is no fixed course. In the registration trials, median treatment exposure was approximately six to seven cycles, with durable responders remaining on therapy considerably longer.

## **Where Reserve Meds fits in Datroway cases**

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Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, do not replace CDSCO or the DCGI, and do not replace the dispensing hospital pharmacy or the licensed specialty importer. What we do is orchestrate US specialty-wholesaler sourcing through the Daiichi/AstraZeneca authorised channel under DSCSA serialisation, validated 2 to 8 degree Celsius cold-chain logistics with IATA-compliant qualified shippers and continuous temperature monitoring through to handoff, and the documentation kit your oncologist needs for the Form 12A filing including the ILD-readiness language. No prior Reserve Meds closed case experience exists for Datroway in India as of this review, so standard NPP coordination applies with particular attention to the dispensing institution's ILD-monitoring capacity and ophthalmologic access. A single named coordinator carries the case from intake through Cycle 1 and into the every-three-week maintenance cadence.

## **Next step**

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If an adult patient in India has HR+/HER2-negative unresectable or metastatic breast cancer and the treating oncologist is considering Datroway after prior endocrine therapy and chemotherapy in the metastatic setting, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your oncologist and an indicative cost range.

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*This guide is informational, not medical or legal advice. The named-patient framework requires a licensed Indian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.*