Datroway

Iraq · access guide

Datroway access in Iraq: the KIMADIA / MOH named-patient pathway

Last reviewed 2026-05-18 by Reserve Meds clinical and regulatory team.

Quick orientation

Patients in Iraq access Datroway (datopotamab deruxtecan-dlnk) for previously treated unresectable or metastatic HR-positive HER2-negative breast cancer, and EGFR-mutant non-small cell lung cancer in subsequent indications through the KIMADIA / MOH named-patient pathway, a the Iraqi State Company for Marketing Drugs and Medical Appliances (KIMADIA) under the Ministry of Health-administered mechanism that allows a Iraqi-licensed physician at a registered facility to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in IQD.

Why Iraqi patients need Datroway through the named-patient pathway

The Republic of Iraq operates a structured pharmaceutical regulatory environment. Datroway (datopotamab deruxtecan-dlnk) is regulated through KIMADIA / MOH (the Iraqi State Company for Marketing Drugs and Medical Appliances (KIMADIA) under the Ministry of Health) channels, and a Iraqi family asking for Datroway is rarely asking for a medicine that does not exist locally. They are usually asking for a precise version of it that the local market has not caught up to.

Four converging patterns drive these cases. First, indication lag. Datroway's newer FDA-approved indications and dosing expansions often reach local registration 12 to 36 months after the US label. A family whose treating physician has documented a clear FDA-label fit may still find that the local label has not caught up. Second, presentation gaps. The exact strength, weight-banded dose, or pen format the prescriber needs may not be stocked at the local agent even when the medicine is registered. Third, payer denial. out-of-pocket cash (frequently USD) payment, supplemented by the MOH public hospital schemes for citizens, limited employer-paid plans through AAIB Insurance, Iraq Insurance Company, and Gulf Insurance Group Iraq, and the Iraqi Red Crescent compassionate support fund for specified rare-disease cases each assess specialty therapies case by case, and step-therapy or formulary rules often produce denials even when the drug is on the local register. Cash-pay families pursue cross-border supply rather than wait through appeals. Fourth, continuity of supply. When a US-stable patient relocates to Iraq or visits family for an extended period, maintaining the original FDA-sourced regimen matters more than switching to a different local presentation.

In each pattern, the KIMADIA / MOH named-patient pathway is the mechanism that connects a Iraqi-licensed physician's clinical decision with US-sourced, FDA-labeled product for a specific patient. Clinically, Datroway is a TROP2-directed antibody-drug conjugate with a topoisomerase I inhibitor (deruxtecan) payload connected via a cleavable tetrapeptide-based linker, administered by IV infusion every three weeks, and the named-patient route preserves that mechanism rather than substituting a non-equivalent local option.

The KIMADIA / MOH named-patient pathway for Datroway

The pathway for a Iraqi-licensed physician to obtain a medicine that is not registered or not stocked locally is the named-patient import authorisation administered jointly by the Iraqi State Company for Marketing Drugs and Medical Appliances (KIMADIA) and the Ministry of Health Department of Drug Registration, which allows a treating physician at a registered tertiary facility (typically within the Baghdad, Basra, or Erbil Medical City networks, or a licensed private hospital) to apply for the import of an unregistered medicine for a specific named patient where the medicine is approved by a recognised reference authority and no clinically equivalent locally registered alternative is suitable; the Kurdistan Region of Iraq operates a parallel authorisation route through the KRG Ministry of Health. The framework allows registered healthcare facilities to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. For Datroway specifically, the clinical justification typically frames the case around the precise FDA-approved indication and the documented gap in the local route.

A complete application includes a clinical justification letter from the treating physician (diagnosis, severity, prior therapies, why this specific drug, why the locally stocked option is not suitable for this case), the treating physician's Iraqi medical license verification through the Iraqi Medical Association and the MOH Department of Drug Registration, an anonymised patient identifier where the KIMADIA / MOH submission allows, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity requested, intended treatment duration), the destination dispensing facility name, license number, and pharmacy in charge, and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Datroway, the clinical justification angle typically rests on one or more of three documented elements: a pediatric or weight-banded request that fits the FDA label but not the local label, a denied biologic or specialty claim where prior step-therapy has been documented, or a continuity-of-supply request for a patient previously stabilised on the US-sourced presentation. The treating physician documents the relevant clinical criteria for the prescribed indication: severity scores, biomarker levels, prior therapy failures, and the rationale for Datroway versus the next-in-line local alternative.

Approval timelines for routine cases are typically 21 to 45 business days. Complex cases (rare indication, larger quantities, first import of a given pediatric or weight-banded format) can extend to 8 to 14 weeks. KIMADIA / MOH retains discretion on timing, and we do not promise specific durations.

Where Datroway gets dispensed in Iraq

A small group of Iraqi institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Tertiary and major private hospitals that meet this profile include Baghdad Medical City Complex in Baghdad, Basra Teaching Hospital and the Basra Oncology Center, and Hiwa Cancer Hospital in Sulaymaniyah. Each maintains pharmacy infrastructure appropriate to the storage requirements of the imported medicine (2 to 8 degrees Celsius cold-chain for biologics, ambient storage for oral therapies, ultra-cold or specialised handling where the FDA label requires it).

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a specialty importer that holds a pharmaceutical establishment license and files the KIMADIA / MOH application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's outpatient or specialty pharmacy under chain-of-custody documentation.

Real cost picture for Datroway in Iraq

US WAC for Datroway runs in the range of USD 179,400 to USD 210,600 per year at the standard FDA-labelled regimen for previously treated unresectable or metastatic HR-positive HER2-negative breast cancer, and EGFR-mutant non-small cell lung cancer in subsequent indications. IQD is trading at approximately 1,310 IQD to 1 USD at the official rate, with specialty medicines typically priced in US dollars at the private hospital pharmacy counter, so the annual reference range converts to roughly IQD 235,014,000 to IQD 275,886,000 for the drug itself at US WAC equivalents.

International logistics for shipment to Iraq typically runs USD 500 to USD 1800 depending on destination city, urgency, and presentation (cold-chain biologics carry the higher end of the range; ambient oral solids the lower). The Republic of Iraq customs and KIMADIA / MOH permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, out-of-pocket cash (frequently USD) payment, supplemented by the MOH public hospital schemes for citizens, limited employer-paid plans through AAIB Insurance, Iraq Insurance Company, and Gulf Insurance Group Iraq, and the Iraqi Red Crescent compassionate support fund for specified rare-disease cases each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation. We do not promise coverage from any insurer. US manufacturer copay cards and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage.

Typical timeline for Datroway in Iraq

KIMADIA / MOH routine processing is typically 21 to 45 business days from a complete filing. International logistics adds 2 to 5 additional days depending on whether the presentation is ambient or cold-chain, the dispensing city, and customs clearance. End-to-end, most routine adult cases complete within 3 to 6 weeks from first complete documentation. Pediatric, weight-banded, or first-import cases can run slightly longer because presentation selection and first-import scrutiny can extend KIMADIA / MOH review.

For temperature-sensitive products, the dispensing facility must maintain validated storage with continuous monitoring; the manufacturer's room-temperature excursion runway on the FDA label informs how we plan the shipping lane, and the cold chain is broken only at the dispensing pharmacy under documented control.

When a case is on a clinical clock (a flare, a new diagnosis with an active disease, or a treatment cycle scheduled at the dispensing centre), the practical question is which step controls the timeline. In our experience the binding step is rarely the KIMADIA / MOH review itself when the application is filed clean; it is usually documentation completeness on the prescriber's side or, for cold-chain biologics, the dispensing facility's storage and monitoring confirmation. The intake is where we lock the case-team contact, gather the documents in parallel, and start the US sourcing clock so that approval and product land in the same week rather than serially.

What your physician needs to provide

For a Iraqi-licensed specialist prescribing Datroway through the KIMADIA / MOH pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's confirmed diagnosis for previously treated unresectable or metastatic HR-positive HER2-negative breast cancer, and EGFR-mutant non-small cell lung cancer in subsequent indications, severity assessment (scoring instrument, biomarker, imaging, or biopsy as appropriate for the indication), prior therapy history including first-line options tried, and a clinical rationale for why Datroway is the appropriate next step given a TROP2-directed antibody-drug conjugate with a topoisomerase I inhibitor (deruxtecan) payload connected via a cleavable tetrapeptide-based linker, administered by IV infusion every three weeks.

The letter also specifies the exact dosing plan per the FDA-approved label: starting dose, maintenance dose, route of administration, schedule, and intended duration of therapy. Monitoring plan should reference any baseline laboratory or imaging requirements specific to Datroway (full blood count, liver function, infection screen, ophthalmology assessment, or pregnancy testing where the FDA label requires it), planned follow-up intervals, and dose-modification criteria for the most common adverse events.

The treating physician's Iraqi license number, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. For cold-chain or specialty-handling products, the dispensing pharmacy's documented storage protocol and continuous-temperature-monitoring log are part of the chain-of-custody record we share with the importer.

Common questions about Datroway in Iraq

Will out-of-pocket cash (frequently USD) payment, supplemented by the MOH public hospital schemes for citizens, limited employer-paid plans through AAIB Insurance, Iraq Insurance Company, and Gulf Insurance Group Iraq, and the Iraqi Red Crescent compassionate support fund for specified rare-disease cases cover this? Each insurer assesses named-patient imports case by case. Some reimburse fully when Datroway is on their formulary even if not currently stocked, some reimburse a percentage subject to copay, and many require pre-authorisation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Is the FDA-approved indication recognised by KIMADIA / MOH? The KIMADIA / MOH named-patient pathway exists precisely to permit access when the local registration or stocking lags the FDA label. The application documents the FDA indication, the reference-authority approval, and the local gap; KIMADIA / MOH review focuses on the clinical justification rather than re-litigating the FDA decision.

My physician is licensed in one region and the hospital is in another. Is that fine? Any Iraqi-licensed physician practicing in good standing in the jurisdiction of the dispensing facility has signing authority on the clinical justification letter. The Iraqi Medical Association and the MOH Department of Drug Registration verifies the active license; the KIMADIA / MOH application records both the prescribing physician and the dispensing facility.

Can I receive Datroway at home? The dispensing facility must be Iraqi-licensed. The hospital outpatient or specialty pharmacy releases the medicine to you after final verification, and you then administer or self-administer at home where the FDA label permits, after the dispensing pharmacy's training. The cold-chain or controlled-storage handoff ends at the dispensing pharmacy; home storage and any handling protocol are part of your patient onboarding kit.

What about competitors or alternative therapies in the same class? Choice of therapy depends on the patient's full phenotype, prior therapy, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not substitute, advise on substitution, or promote one brand over another.

Where Reserve Meds fits in Datroway cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, we do not replace KIMADIA / MOH, and we do not replace your dispensing pharmacy. For Datroway specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated logistics (cold-chain with continuous temperature logging where the FDA label requires it) into Iraq, and assign a single named coordinator through the case. Standard named-patient coordination under our specialty playbook applies. Presentation selection, dose-band confirmation, and patient onboarding for self-administration where applicable are the recurring operational fundamentals we expect for this drug.

Operationally, a typical Datroway case runs across four parallel tracks. The clinical track is the physician's: justification letter, dosing plan, monitoring schedule, and the next patient-facing follow-up. The regulatory track is the KIMADIA / MOH application packaged by the importer; we provide the documentation template, the dispensing facility license check, and the chain-of-custody attestation. The logistics track is the US-side sourcing and the validated international shipment with continuous temperature logging and customs broker coordination. The patient-experience track is the named coordinator who keeps everyone aligned on dates, addresses dispensing-pharmacy questions, and confirms the medicine has been received and stored correctly. The four tracks are run in parallel rather than in series; that is the operational difference between a 3-week and a 9-week case.

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.
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