Keytruda

Iraq · access guide

How to access Keytruda from Iraq, the named-patient import pathway, 2026

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

An Iraqi patient with a broad set of FDA-approved indications across melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high or mismatch repair deficient tumors, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high tumors, and triple-negative breast cancer among others may receive a prescription for Keytruda (pembrolizumab) from their treating oncologist. Keytruda is FDA-approved in the United States and manufactured by Merck. It is a humanised PD-1 immune checkpoint inhibitor administered by intravenous infusion. Local availability of Keytruda in Iraq 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 ICDA 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

Keytruda is a humanised PD-1 immune checkpoint inhibitor. Mechanism: a humanised IgG4 monoclonal antibody that binds PD-1 and blocks its interaction with PD-L1 and PD-L2, restoring T-cell antitumor activity. Dosing: 200 mg every three weeks or 400 mg every six weeks by intravenous infusion per FDA labeling, with indication-specific schedules. Baseline workup per FDA labeling includes complete blood count, comprehensive metabolic panel, thyroid function, baseline imaging, and infectious disease screen as clinically indicated. Other important warnings include immune-mediated adverse reactions including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and severe skin reactions; infusion reactions; complications of allogeneic transplant in patients with classical Hodgkin lymphoma; and embryo-fetal toxicity. Your oncologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Keytruda legally importable into Iraq?

Yes, through the Iraqi Drug and Medical Appliance Regulatory Authority (ICDA) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. Iraq 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 ICDA named-patient route allows an Iraqi-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 Keytruda.
2. **Baseline screening.** Complete blood count, comprehensive metabolic panel, thyroid function, baseline imaging, and infectious disease screen as clinically indicated are confirmed and documented.
3. **ICDA 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 Merck's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Keytruda 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 Keytruda as the indicated next step
- Verification of their Iraqi 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 (200 mg every three weeks or 400 mg every six weeks by intravenous infusion per FDA labeling, with indication-specific schedules)
- A monitoring plan covering biomarker result (PD-L1 CPS or TPS, MSI/MMR, TMB, or tumor-specific genomic test), immune-mediated AE monitoring plan, and prior-therapy summary

Reserve Meds provides a physician documentation kit tailored for PD-1 checkpoint inhibitor therapies, including the templates ICDA 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 200 mg every-3-week cycle of Keytruda sits in an indicative 2026 band of approximately USD 11,000 to 15,000. International logistics, ICDA 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.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Keytruda specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for ICDA review, including PD-1 checkpoint inhibitor class templates.
- **Cold-chain logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility with continuous temperature loggers.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating oncologist, and dispensing sits with the licensed Iraqi pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Iraq? Yes, when executed through the ICDA named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at Iraqi tertiary centers.

Will my private health insurance cover this? Cash-pay is the default posture. Cash-pay is the default posture in Iraq; private plan coverage of specialty imports is limited and case-by-case. We supply documentation for your submission but do not process insurance claims.

How does cold-chain affect timing? Keytruda ships refrigerated. We use validated packaging with continuous temperature monitoring, and arrival temperature data is logged on every shipment.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Iraqi tertiary centers (the National Cancer Research Center and Baghdad Medical City teaching hospitals) have encountered. Our documentation kit is written for first-time applicants and tracks what ICDA reviewers commonly ask for.

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.
Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.
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