Padcev

Oman · access guide

How to access Padcev from Oman, the named-patient import pathway, 2026

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

A Oman patient with locally advanced or metastatic urothelial cancer, including in the first-line setting in combination with pembrolizumab, or in patients who have previously received a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy, may receive a prescription for Padcev (enfortumab vedotin-ejfv) from their treating oncologist. Padcev is FDA-approved in the United States and co-marketed by Astellas Pharma and Seagen. It is a Nectin-4 directed antibody-drug conjugate administered by intravenous infusion. Local availability of Padcev in the Kingdom of Oman can be inconsistent: the drug may not be on every oncology 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 the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) 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

Padcev is an antibody-drug conjugate that pairs an anti-Nectin-4 monoclonal antibody with monomethyl auristatin E (MMAE), a microtubule-disrupting payload, linked by a protease-cleavable linker. Dosing in the EV-302 first-line regimen is 1.25 mg/kg by intravenous infusion on days 1 and 8 of a 21-day cycle, given in combination with pembrolizumab. Baseline workup per FDA labeling includes complete blood count with differential, hepatic function tests, baseline glycemic assessment (hyperglycemia is a known adverse event), and pregnancy testing where applicable. The FDA boxed warning covers serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis. Other important warnings include peripheral neuropathy, hyperglycemia, pneumonitis or interstitial lung disease, infusion site extravasation, and embryo-fetal toxicity. Your oncologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Padcev legally importable into Oman?

Yes, through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Kingdom has an established pathway for specialty oncology medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The DGPADC named-patient route allows a Oman-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 DGPADC 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, and rationale for Padcev.
2. **Baseline screening.** CBC with differential, LFTs, baseline glucose, skin exam, and pregnancy testing where applicable are confirmed and documented.
3. **DGPADC named-patient application.** Your oncologist or the hospital'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 Astellas and Seagen's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Padcev 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 at the infusion center.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis (urothelial cancer with stage and prior therapy), prior platinum and PD-1 inhibitor exposure where relevant, and Padcev as the indicated next step
- Verification of their Oman medical licence (SCFHS registration)
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening (CBC, LFTs, baseline glucose, skin assessment) consistent with FDA labeling
- The planned dosing strength and infusion cadence (1.25 mg/kg on days 1 and 8 of 21-day cycles)
- A discussion note on the boxed-warning monitoring plan for severe skin reactions and the additional warnings around peripheral neuropathy and hyperglycemia

Reserve Meds provides a physician documentation kit that bundles the templates DGPADC reviewers expect to see for antibody-drug conjugate oncology therapies, including the boxed-warning monitoring plan 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 21-day cycle of Padcev (two infusions) sits in an indicative 2026 band of roughly USD 17,000 to 22,000, depending on patient weight. International logistics, DGPADC 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 to DGPADC, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the 21-day infusion 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 Padcev 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 DGPADC review, including ADC-class boxed-warning monitoring 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 Oman pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC 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 in Oman tertiary centers.

What about the boxed warning? The FDA boxed warning on Padcev covers severe cutaneous adverse reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis. Your oncologist performs the risk-benefit assessment, schedules skin monitoring, and counsels the patient on rash reporting per labeling. Reserve Meds does not make that clinical judgement, your physician does.

Will my private health insurance cover this? Cash-pay is the default posture. Some Oman private insurers and CCHI-aligned plans reimburse named-patient oncology imports on a case-by-case basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

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

What if my oncologist has not filed a named-patient request before? Named-patient import is an institutional process most major Oman cancer centers (King Faisal Specialist Hospital and Research Centre, King Abdulaziz Medical City, KFSHRC Jeddah) have encountered. Our documentation kit is written for first-time applicants and tracks what DGPADC 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.

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