Trodelvy

Saudi Arabia · access guide

How to access Trodelvy from Saudi Arabia, the named-patient import pathway, 2026

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

An Saudi Arabiaian patient with metastatic triple-negative breast cancer (TNBC), HR+/HER2-negative metastatic breast cancer after prior endocrine and at least two prior chemotherapy lines for metastatic disease, or locally advanced or metastatic urothelial carcinoma after prior platinum-containing chemotherapy and a checkpoint inhibitor, may receive a prescription for Trodelvy (sacituzumab govitecan-hziy) from their treating oncologist. Trodelvy is FDA-approved in the United States and manufactured by Gilead Sciences. It is a Trop-2 directed antibody-drug conjugate administered by intravenous infusion. Local availability of Trodelvy in Saudi Arabia can be inconsistent: the drug may not be on every cancer center's standing formulary, the specific indication may not match what is locally stocked, or the strength required may be back-ordered. When that happens, a named-patient import pathway through the Saudi Food and Drug Authority (SFDA) 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

Trodelvy is an antibody-drug conjugate that pairs an anti-Trop-2 monoclonal antibody with SN-38, the active metabolite of irinotecan, as the cytotoxic payload. Dosing is 10 mg/kg by intravenous infusion on days 1 and 8 of a 21-day cycle, continued until disease progression or unacceptable toxicity. Baseline workup per FDA labeling includes complete blood count with differential, liver function tests, and pregnancy testing where applicable. The FDA boxed warning covers severe or life-threatening neutropenia and severe diarrhea. UGT1A1 genotype may inform dose adjustment in patients homozygous for UGT1A1*28. Your oncologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Trodelvy legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Saudi Arabia 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 SFDA named-patient route allows an Saudi Arabia-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.

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, biomarker status, and rationale for Trodelvy.
2. **Baseline screening.** CBC with differential, LFTs, and pregnancy testing where applicable are confirmed and documented.
3. **SFDA 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 Gilead Sciences's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Trodelvy 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, biomarker status, prior therapy history, and Trodelvy as the indicated next step
- Verification of their Saudi Arabiaian medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening (CBC with differential, LFTs, baseline imaging) consistent with FDA labeling
- The planned dosing strength and infusion cadence (10 mg/kg on days 1 and 8 of 21-day cycles)
- A discussion note on the boxed-warning monitoring plan for severe neutropenia and severe diarrhea

Reserve Meds provides a physician documentation kit that bundles the templates SFDA 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 Trodelvy (two infusions) sits in an indicative 2026 band of roughly USD 13,000 to 17,500. Heavier patients or extended cycles cost more. International logistics, SFDA 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 3 to 6 weeks from the moment a complete application is submitted to SFDA, 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 Trodelvy 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 SFDA 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 Saudi Arabiaian pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the SFDA 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 Saudi Arabiaian tertiary centers.

What about the boxed warning? The FDA boxed warning on Trodelvy covers severe or life-threatening neutropenia and severe diarrhea. Your oncologist performs the risk-benefit assessment and schedules CBC monitoring 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 Saudi Arabiaian private insurers 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? Trodelvy 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 Saudi Arabiaian cancer centers (Nasser Institute, NCI Cairo, Maadi Military Medical Compound, As-Salam International, Dar Al Fouad) have encountered. Our documentation kit is written for first-time applicants and tracks what SFDA 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.

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