

Pomalyst

Saudi Arabia · access guide

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

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

A Saudi Arabia patient with relapsed or refractory multiple myeloma after at least two prior therapies including lenalidomide and a proteasome inhibitor, or with Kaposi sarcoma after highly active antiretroviral therapy (HAART) failure or in HIV-negative patients, may receive a prescription for Pomalyst (pomalidomide) from their treating hematologist or oncologist. Pomalyst is FDA-approved in the United States and manufactured by Bristol Myers Squibb. It is an oral immunomodulatory drug (IMiD) administered by capsule. Local availability of Pomalyst in Saudi Arabia 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 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

Pomalyst is an oral immunomodulatory drug. Mechanism: a thalidomide analogue that binds cereblon, a substrate receptor of the CRL4 E3 ubiquitin ligase, with greater potency than lenalidomide and activity in some lenalidomide-refractory disease. Dosing: typically 4 mg orally once daily on days 1 through 21 of repeated 28-day cycles, per FDA labeling, in combination with dexamethasone for myeloma. Baseline workup per FDA labeling includes pregnancy testing in females of reproductive potential under the Pomalyst REMS program, CBC with differential, comprehensive metabolic panel, and venous thromboembolism risk review. Other important warnings include embryo-fetal toxicity (boxed warning), venous and arterial thromboembolism (boxed warning), hepatotoxicity, dizziness and confusional state, and second primary malignancies. Your hematologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Pomalyst legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient and personal-use import framework, coordinated through a Saudi Arabia-licensed treating facility's pharmacy. The Saudi Arabia 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 SFDA named-patient route allows a 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, with approval issued on a per-patient, per-cycle quantity basis.

How the pathway works, step by step

1. **Consultation with your treating hematologist.** The prescribing decision is clinical. Your hematologist documents the indication, prior lenalidomide and PI exposure for myeloma, and rationale for Pomalyst.
2. **Baseline screening.** Pregnancy testing under REMS-equivalent process for females of reproductive potential, CBC with differential, comprehensive metabolic panel, and VTE risk review are confirmed and documented.
3. **SFDA named-patient application.** Your hematologist 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 Bristol Myers Squibb's authorised distribution under DSCSA chain-of-custody.
5. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your hematologist initiates therapy.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis (r/r MM post lenalidomide and PI, or Kaposi sarcoma per labeled setting), prior therapies, and Pomalyst as the indicated next step
- Verification of their Saudi Arabia medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above), including pregnancy testing where applicable
- The planned dosing regimen (4 mg orally on days 1 through 21 of 28-day cycles, with dexamethasone for myeloma, per FDA labeling)
- A monitoring plan covering CBC at regular intervals, pregnancy surveillance for females of reproductive potential, and VTE prophylaxis plan

Reserve Meds provides a physician documentation kit tailored for IMiD therapies, including the templates SFDA 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 typical 28-day cycle of Pomalyst at 4 mg dosing sits in an indicative 2026 band of approximately USD 23,000 to 27,000. International logistics, SFDA documentation handling, 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 cycle 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 Pomalyst 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 IMiD class templates.
- **Logistics.** Internationally tracked shipment to your named dispensing facility with tamper-evident packaging.
- **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 hematologist, and dispensing sits with the licensed Saudi Arabia 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 at Saudi Arabia tertiary centers.

Will my private health insurance cover this? Cash-pay is the default posture. Some Saudi Arabia private insurers (Daman, AXA, Mednet-administered plans) reimburse named-patient 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 Pomalyst differ from Revlimid? Both are oral cereblon-binding IMiDs. Pomalidomide is more potent and retains activity in some lenalidomide-refractory myeloma, which is why FDA labeling positions Pomalyst after lenalidomide and a proteasome inhibitor have already been tried. The choice between continuing IMiD therapy and switching class is a clinical decision your hematologist will make.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Saudi Arabia tertiary centers (Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, American Hospital Dubai, and Mediclinic City Hospital) 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.

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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