

## Keytruda

Saudi Arabia · access guide

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

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Saudi Arabia patient with a solid tumour for which immunotherapy is indicated, non-small cell lung cancer, melanoma, head and neck cancer, urothelial cancer, triple-negative breast cancer, renal cell carcinoma, certain gastrointestinal cancers, and other FDA-approved settings, may receive a prescription for Keytruda (pembrolizumab) from their treating oncologist. Keytruda is FDA-approved, developed by Merck, and is one of the most widely used anti-PD-1 immunotherapies across oncology. In Saudi Arabia, Keytruda is accessible through hospital pharmacies for several indications; for other indications or where supply timing is an issue, the Ministry of Public Health (SFDA) named-patient import route is available.

This guide explains the legal pathway, what documentation your physician needs, typical timing and cost bands, and where Reserve Meds fits in.

## The clinical situation

Keytruda is an anti-PD-1 monoclonal antibody given as an intravenous infusion every three or six weeks in an outpatient oncology setting. Eligibility depends on the specific tumour type, line of therapy, and, for many indications, biomarker testing (PD-L1 expression, microsatellite instability / mismatch-repair status, tumour mutational burden, or others depending on FDA labeling). Pivotal studies have demonstrated extended overall and progression-free survival across multiple indications relative to prior standards. Your oncologist will confirm eligibility, biomarker status where applicable, and set up baseline autoimmune screening and on-treatment monitoring.

## Is Keytruda legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient import framework, administered in coordination with the Saudi Arabia Council for Healthcare Practitioners (QCHP)-licensed physician and the treating hospital pharmacy. The named-patient mechanism allows a Saudi Arabia-licensed physician to request import of a medicine not locally registered, or not locally available in the formulation or quantity required, when: (a) the medicine is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent locally registered alternative is suitable, (c) the physician takes clinical responsibility, and (d) chain of custody is documented end to end.

For Keytruda specifically, the infrastructure requirements are modest, an outpatient oncology infusion suite with standard cold-chain storage, and most Saudi Arabia tertiary centres already administer anti-PD-1 therapy routinely.

## How the pathway works, step by step

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1. **Consultation with your treating oncologist.** The decision to prescribe Keytruda is a clinical one, supported by biomarker testing where applicable and a written rationale.
2. **Infusion facility identification.** An oncology day-unit with cold-chain storage is confirmed.
3. **SFDA named-patient application.** Your physician or the hospital pharmacy files the application with clinical rationale, patient reference, product details, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from authorised distribution.
5. **Cold-chain shipment.** The product ships with continuous temperature monitoring and chain-of-custody documentation.
6. **Arrival and first infusion.** The hospital pharmacy releases doses to the oncology day-unit for administration on your cycle schedule.

## What documentation your physician needs

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Your physician will typically need to provide:

- A clinical rationale letter confirming tumour type, biomarker status where relevant, line history, and Keytruda as the indicated treatment
- Verification of their Saudi Arabia medical licence (QCHP)
- Identification of the administering infusion facility
- Patient identifier (QID reference where required)
- Planned dosing schedule (typically 200 mg every three weeks or 400 mg every six weeks, depending on indication)

Reserve Meds provides a physician documentation kit that bundles the templates SFDA reviewers expect to see, including the immune-related adverse event surveillance plan that is standard for anti-PD-1 therapy.

## Costs and timing

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Keytruda's US cash-pay drug-only reference price sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 10,000-12,000 per 200 mg dose, with typical cycle costs driven by the selected dosing interval. Cold-chain logistics, SFDA documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a full transparent quote at the start of intake.

Indicative timing for the first infusion after cohort intake opens is 10-21 days from the moment a complete SFDA application is submitted. Subsequent cycles ship on a rolling basis against your infusion calendar.

*Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.*

A culturally-aware note: many Saudi Arabia families prefer local continuity of care and are well served by the country's tertiary oncology infrastructure. Named-patient import supplements, rather than replaces, local management; all administration and monitoring is by your Saudi Arabia-based oncology team.

## Reserve Meds's role

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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.
- **Documentation.** Regulatory package for your physician and for SFDA review.
- **Logistics.** Cold-chain, temperature-monitored shipment coordination.
- **Concierge case lead.** A named point of contact for your family and your physician through intake and cycle-to-cycle refills.

**What we do not do:** we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating oncologist and the administering infusion facility.

## Frequently asked

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**Is this legal in Saudi Arabia?** Yes, when executed through the SFDA named-patient framework with appropriate documentation. Cross-border named-patient import is a routine mechanism across Saudi Arabia oncology. See our trust and compliance page.

**My tumour isn't one of the classic Keytruda indications, can it still be prescribed?** Keytruda's FDA label covers many tumour types, plus a tissue-agnostic indication for mismatch-repair-deficient / MSI-high tumours. Your oncologist will review FDA labeling and determine whether your specific tumour and biomarker profile meet an approved indication.

**What are immune-related adverse events?** Anti-PD-1 therapy can produce autoimmune inflammation in various organs (thyroid, colon, liver, lung, skin, others). These are recognised, and management protocols are well established. Your oncology team will brief you.

**Can I switch between three-weekly and six-weekly dosing?** FDA labeling supports both schedules for several indications at the oncologist's discretion. Your doctor will choose the schedule that fits your care plan.

**Will insurance cover this?** Cash-pay is the default for named-patient supply. Some Saudi Arabia private insurers consider reimbursement case by case; we supply documentation for your submission but do not process insurance claims directly.

### *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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**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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