Sotyktu

Saudi Arabia · access guide

How to access Sotyktu 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 moderate-to-severe plaque psoriasis who is a candidate for systemic therapy or phototherapy may receive a prescription for Sotyktu (deucravacitinib) from their treating dermatologist. Sotyktu is FDA-approved in the United States and manufactured by Bristol Myers Squibb. It is an oral, once-daily selective TYK2 inhibitor, mechanistically distinct from the JAK1/2/3 inhibitor class, approved for adults whose psoriasis has not responded adequately to topicals or who are otherwise systemic-eligible. Local availability in Saudi Arabia varies by emirate and by pharmacy; when the specific product or strength is not in stock, a named-patient import route through the Ministry of Health and Prevention (SFDA) remains legitimate for the patient whose dermatologist has already prescribed the drug.

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

The clinical situation

Sotyktu is an oral allosteric TYK2 inhibitor taken once daily. The usual dose is 6 mg once daily, with or without food. TYK2 inhibition is mechanistically distinct from JAK1/2/3 inhibition, and the FDA labeling for Sotyktu does not include the boxed warning that applies to the broader JAK class; nonetheless, pre-treatment screening per labeling includes tuberculosis, hepatitis B and C serology, baseline CBC, and liver function tests. Vaccination status should be reviewed, and live vaccines are not recommended during therapy. Your dermatologist will document psoriasis severity (PASI, BSA, IGA) and prior therapy history before starting Sotyktu, and schedule follow-up monitoring.

Is Sotyktu legally importable into Saudi Arabia?

Yes, through the SFDA named-patient / personal-use import framework, coordinated with the treating facility's pharmacy. The Saudi Arabia has a mature pathway for specialty dermatology medicines approved by reference authorities but not stocked locally for the specific strength or indication.

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 such as the US FDA or EMA, (b) no clinically equivalent locally available alternative is suitable for the patient, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the dispensing pharmacy. Dubai Health Authority and Department of Health Abu Dhabi issue complementary approvals where the dispensing facility sits inside their jurisdiction.

How the pathway works, step by step

1. **Consultation with your treating dermatologist.** The prescribing decision is clinical. Your dermatologist documents severity, prior therapy history, and rationale for Sotyktu specifically.
2. **Baseline screening.** TB, viral hepatitis, CBC, and LFTs are completed and documented per FDA labeling; vaccination status is reviewed.
3. **SFDA named-patient application.** Your dermatologist or hospital pharmacy files the application with clinical rationale, patient reference, strength, quantity, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from BMS authorised distribution under DSCSA chain-of-custody.
5. **Shipment.** Sotyktu is an oral tablet with standard room-temperature storage; shipment moves with tamper-evident packaging and tracking documentation.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription and therapy begins.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming the plaque psoriasis diagnosis, severity scoring (PASI, BSA, IGA), prior therapy history (topicals, phototherapy, and any systemic or biologic agents), and Sotyktu as the indicated treatment
- Verification of their Saudi Arabia medical licence (SFDA / DHA / DoH)
- A patient identifier (anonymised reference preferred)
- Documented pre-treatment screening (TB, hepatitis, CBC, LFTs) and vaccination review
- The planned dosing and refill cadence (6 mg once daily, typically assessed for response at week 16)

Reserve Meds provides a physician documentation kit that bundles the templates SFDA reviewers expect for oral specialty dermatology imports.

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 30-tablet month supply of Sotyktu 6 mg sits in an indicative 2026 band of roughly USD 6,500 to 7,500. International logistics, SFDA documentation handling, and concierge coordination add incremental cost. The delivered quote we issue at intake itemises each line so nothing is hidden.

Indicative timing, not a guarantee, for first dose after cohort intake opens is 7 to 14 days 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 thereafter.

; service availability is limited to our first cohort. All timelines are indicative, not guarantees. If your clinical situation is time-sensitive, flag that when you

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Sotyktu 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 dermatologist and for SFDA / DHA / DoH review.
- **Logistics.** Tamper-evident, internationally tracked shipment to your named dispensing pharmacy.
- **Concierge case lead.** A named point of contact for your family and your dermatologist across the full case arc.

We are a coordinator, not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating dermatologist, and dispensing sits with the licensed Saudi Arabia pharmacy of record.

FAQ

Is Sotyktu a JAK inhibitor?

Sotyktu is an allosteric TYK2 inhibitor, mechanistically distinct from the JAK1/2/3 class. Its FDA labeling does not carry the class boxed warning that applies to JAK1/2/3 inhibitors. Your dermatologist will still perform baseline screening and periodic monitoring per labeling.

How does Sotyktu compare to biologics for psoriasis?

Sotyktu is an oral once-daily small molecule, which some patients prefer over injectable biologic therapy. Comparative effectiveness varies by case; your dermatologist will weigh options against your severity, comorbidities, and preferences.

When is response typically assessed?

FDA labeling references a week-16 response assessment as a common decision point. Your dermatologist sets the follow-up schedule for your case.

What if my dermatologist has not filed a SFDA named-patient request before?

The process is institutional and your hospital will have encountered it. Our documentation kit is written for first-time applicants.

Will private insurance cover this?

Cash-pay is the default posture. Some Saudi Arabia private insurers reimburse named-patient imports on a case-by-case basis; we supply documentation 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.

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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